NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by 1st submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Due to time restraints, the Secretary of State's Office will no longer edit the text of proposed rules. We will continue to make numbering and labeling changes as necessary.

Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 12. NATURAL RESOURCES

CHAPTER 7. OIL AND GAS CONSERVATION COMMISSION

PREAMBLE

1. **Sections Affected** — **Rulemaking Action**
   R12-7-121 — Amend
   R12-7-125 — Amend

2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
   Authorizing statutes: A.R.S. §§ 27-516(A) and 27-656

   Implementing statutes: A.R.S. §§ 27-516(A)(1) and (2), 27-652(A), and 27-661

3. **A list of all previous notices concerning the rules:**
   Notice of Rulemaking Docket Opening: 4 A.A.R. 475, February 13, 1998.
   Notice of Proposed Rulemaking: 4 A.A.R. 506, February 20, 1998.
   Notice of Termination of Rulemaking: 4 A.A.R. 1452, June 26, 1998.
   Notice of Rulemaking Docket Opening: 4 A.A.R. 3049, October 16, 1998.

4. **The name and address of agency personnel with whom persons may communicate regarding the rule:**
   Name: Steven L. Rauzi, Oil & Gas Program Administrator

   Address: Arizona Geological Survey
   416 West Congress, Suite 100
   Tucson, Arizona 85701-1315

   Telephone: (520) 770-3500

   Fax: (520) 770-3505

5. **An explanation of the rule, including the agency's reasons for initiating the rule:**
   R12-7-121 specifies completion and reporting requirements for wells. R12-7-125 specifies requirements when drilling, testing, injection, or production operations are suspended for 60 or more days. These rules are being amended to improve clarity and understandability.

6. **A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where the public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:**
   None.

7. **A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**
   Not applicable.

8. **The preliminary summary of the economic, small business, and consumer impact:**
   These rules directly impact companies drilling for oil, gas, and geothermal resources. The rules are mostly procedural in nature and will not significantly impact the economy or have a significant impact upon small businesses or consumers. The proposed rulemaking will benefit the regulated community by clarifying reporting requirements.

9. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name: Steven L. Rauzi, Oil & Gas Program Administrator

Address: Arizona Geological Survey
416 W. Congress, Suite 100
Tucson, Arizona 85701-1315

Telephone: (520) 770-3500

Fax: (520) 770-3505

10. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

Date: January 15, 1999

Time: 10 a.m.

Location: 1700 W. Washington, Room 500
Phoenix, Arizona 85007

Nature: Oral proceeding to adopt amended rules

11. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**
Not applicable.

12. **Incorporation by reference and their location in the rules:**
None.

13. **The full text of the rules follows:**

TITLE 12. NATURAL RESOURCES

CHAPTER 7. OIL AND GAS CONSERVATION COMMISSION

ARTICLE 1. OIL, GAS, HELIUM, AND GEOTHERMAL RESOURCES

Section
R12-7-121. Well Completion and Filing Requirements
R12-7-125. Temporary Abandonment

ARTICLE 1. OIL, GAS, HELIUM, AND GEOTHERMAL RESOURCES

R12-7-121. Well Completion and Filing Requirements

A. ~~For the purpose of this rule only, a well shall be determined~~ The commission considers a well ~~to be~~ completed when it is capable of production, has been temporarily abandoned under ~~as provided for in~~ R12-7-125, or has been plugged and abandoned under ~~as provided for in R12-7-126 and~~ R12-7-127.

B. An ~~The~~ operator shall file a completion report with the Commission within 30 days after the completion of a well. The completion report shall contain a description of the well and lease, the casing record, the tubing record, the liner record, the perforation record, the stimulation and cement squeeze record, and data on the initial production and any additional information required by R12-7-125. The operator shall submit other well data including any lithologic, mud, or wireline log; directional survey; core description and analysis; stratigraphic or faunal determination; formation or drill-stem test; formation fluid analysis; and any other similar information or survey to the Commission with the completion report or within 30 days of the completion of drilling. ~~Other well data, including all logs, tests, and surveys shall be filed with the completion report or within 30 days after the completion of the well.~~

C. An ~~The~~ operator shall furnish samples of all cores and cuttings, at a maximum interval of 10 feet, to the Commission within 30 days of removing a ~~the~~ drilling rig from the hole. The operator may furnish core samples in chips. The operator shall: ~~All samples for the Commission shall be handled as follows:~~

1. Wash and dry all ~~All~~ samples; ~~shall be washed and dried.~~
2. Place approximately ~~Approximately~~ 3 tablespoons of each sample ~~shall be placed~~ in an envelope that shows ~~showing~~ the identification of the well where ~~from which~~ the sample originated, the location of the well, the Commission's permit number, and the depth where the sample was taken; and ~~at which the sample was taken.~~
3. Package samples in protective ~~Samples shall be packaged in~~ boxes and ship ~~for protection and shall be shipped~~ prepaid to:
   Oil and Gas Program Administrator
   Arizona Geological Survey
   416 West Congress, Suite 100
   Tucson, AZ 85701
4. ~~Core samples may be furnished in chips and packed and shipped as specified in paragraphs (2) and (3).~~

D. Upon written request by an ~~the~~ operator, the Commission shall keep any well information required by ~~in~~ this Section confidential for ~~a period~~ 6 months after the operator has removed the drilling rig from the hole. ~~not to exceed 6 months from the completion date of a stratigraphic or exploratory hole and for a period not to exceed 2 years from the completion date of a geothermal resources well.~~

R12-7-125. Temporary Abandonment

A. When drilling, injection, or production operations have been suspended for 60 days, an operator ~~the well~~ shall plug and abandon a well under ~~be plugged and abandoned as required in R12-7-126 and~~ R12-7-127 or temporarily abandon the well. ~~unless the operator obtains written permission for tem-~~

~~porary abandonment from the Commission. On drilling wells, the drilling rig shall not be removed from the hole until written permission for temporary abandonment is obtained from the Commission. Permission granted shall be for a period not to exceed 1 year. One-year extensions may be granted.~~

B. An operator may temporarily abandon a well for a period of 1 year if the operator submits a completion report under R12-7-121 containing the following additional information:

1. Evidence of casing integrity including a complete description of the current casing, cementing, and perforation record of the well;
2. The stimulation and cement squeeze record and complete data on the results of any well tests performed to date; and
3. Reasons for temporary abandonment of the well.

~~When requesting temporary abandonment, the operator shall file with the Commission a description of the mechanical condition of the well and a current corrosion, caliper, or cement bond log. The Commission shall not approve temporary abandonment or an extension unless the operator can show that the mechanical condition of the well will prevent damage to the producing zone, prevent contamination of fresh waters or other natural resources, and prevent leakage of any substance at the surface. The Commission may require a mechanical integrity test of the casing before approving or extending temporary abandonment.~~

C. After 1 year, an operator shall plug any temporarily abandoned well unless the Commission grants a 1-year extension upon a showing of good cause by the operator that the well should not be plugged in accordance with R12-7-127. An operator shall prove casing integrity to continue temporary abandonment status. An operator shall plug any well that fails to meet the casing integrity required by R12-7-112.

~~Upon expiration of the period of temporary abandonment or an extension, the well shall be plugged and abandoned, unless the operator can demonstrate to the Commission why the well should not be plugged and abandoned, and a further extension issued.~~

D. Before reentering any temporarily abandoned well, an ~~the~~ operator shall give the Commission at least 10 days' written notice of intent detailing the proposed activity. Within 15 days of completing the proposed activity, the operator shall file a subsequent written report with the Commission fully describing the work performed.

NOTICE OF PROPOSED RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY
SOLID WASTE MANAGEMENT

PREAMBLE

1. **Sections Affected:** — **Rulemaking Action**

Article 14	New Article
R18-13-1401	New Section
R18-13-1402	New Section
R18-13-1403	New Section
R18-13-1404	New Section
R18-13-1405	New Section
R18-13-1406	New Section
R18-13-1407	New Section
R18-13-1408	New Section
R18-13-1409	New Section
R18-13-1410	New Section
R18-13-1411	New Section
R18-13-1412	New Section
R18-13-1413	New Section
R18-13-1414	New Section
R18-13-1415	New Section
R18-13-1416	New Section
R18-13-1417	New Section

2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing Statutes: A.R.S. §§ 41-1003 and 49-104.

Implementing Statutes: A.R.S. §§ 49-761(D), 49-761(G), 49-762, 49-762.03, 49-762.04, 49-762.06, and 49-770.

3. **List of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Termination: 4 A.A.R. 3791, November 13, 1998.
Notice of Docket Opening: 4 A.A.R. 3819, November 13, 1998.

4. **The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name: Kate Cross or Martha L. Seaman

Address: Arizona Department of Environmental Quality
Rule Development Section, M0836A-829
3033 North Central Avenue
Phoenix, Arizona 85012

Telephone: (602) 207-2222

Or toll-free within Arizona: (800) 234-5677, Ext. 2222

Fax: (602) 207-2251

5. **An explanation of the rule, including the agency's reasons for initiating the rule:**

The purpose of this rulemaking is to set forth handling, treatment and disposal standards for biohazardous ("regulated") medical waste.

A. Background for these Proposed Rules

1. The Rule was developed with Considerable Public Participation.

ADEQ originally proposed this rulemaking in June of 1993. A "small quantity generator" exemption proved to be controversial. This exemption allowed small amounts of untreated medical waste in the solid waste stream as long as the waste was properly packaged, and required that landfills accept untreated medical waste from small quantity generators. The Department's rationale for the exemption was to provide regulatory flexibility to dentists, physicians, veterinarians and others, and considered this flexibility justified because of concerns over access to treatment (particularly in rural Arizona) and disproportional cost to this class of generator. Other issues discussed included a stakeholder recommendation that ADEQ simplify the definition of medical waste to make it more consistent with other nationally recognized regulatory definitions, and a recommendation that refrigeration be required only if the waste is capable of decomposing.

ADEQ withdrew the proposed rulemaking and pledged to revisit these controversial issues with persons affected by the rule. To accomplish this, ADEQ identified 6 classes of stakeholders and invited representatives from each class to a series of facilitated medical waste roundtables to discuss the rule provisions. Those classes were: treatment interests; disposer interests (landfills); public interests (interested persons who are members of the public); regulatory interests (other state and county regulators); generator interests; and transport/hauler interests. Roundtable participants in these 2 roundtables included the Arizona Hospital Association, Association of Professionals: Infection Control and Epidemiology, Browning Ferris Industries, Waste Management Incorporated, Arizona Medical Association, Arizona Association of Infectious Disease Physicians, among others.

Approximately 100 persons attended each of the facilitated medical waste roundtable meetings held in February of 1994 and January of 1995. The audience for each consisted of invited panelists and open audience seating. In addition, a third "treatment meeting" attended by approximately 50 persons was held in October of 1994 to discuss technical capabilities of various treatment methods. The second roundtable (held in January, 1995) built upon the shared understanding reached at the first roundtable and discussed information from the treatment meeting. As a result of the 2 roundtables and the treatment meeting, the stakeholders recommended that ADEQ delete the small quantity generator exemption and resolve the access and cost issues related to treatment by allowing treatment alternatives to autoclaving and incineration. Despite prolonged discussion, no group recommendation was reached regarding an appropriate treatment standard. Participants advised ADEQ that agreement on the treatment issue was not possible given competition for market share and recommended that ADEQ determine the treatment standards.

In May of 1996, the Department again proposed rules for handling, treatment and disposal of biohazaroudous ("regulated") medical waste. During the comment period 16 comment letters were received. Several commenters expressed concern over home generated medical sharps deposited in household garbage for collection. In considering the comments, the Department determined that the rule should be changed to address issues raised, and that some of these changes constituted substantial change as described in A.R.S. § 411025(B). Accordingly, a Notice of Supplemental Proposed Rulemaking was published at 2 A.A.R. 47, November 22, 1996.

Work resumed on this rulemaking. In July 1998 the Department received a petition urging it to refrain from requiring all medical waste to be treated before going to a landfill. On September 3, 1998, the Department held a facilitated round table meeting attended by approximately 60 stakeholders, including representatives of the 6 stakeholder groups identified above.

Today's proposed rule builds on this extensive stakeholder involvement process, and retains some changes included in the 1996 Notice of Supplemental Proposed Rulemaking, as well as the views of the Department reached after analysis and consideration of the comments received at the most recent roundtable.

2. Biohazardous Medical Waste Defined

The solid waste "stream" is made up of waste from various sources including household-generated solid waste, hazardous waste, special waste, sludge, biohazardous medical waste, non-biohazardous medical waste among others. All waste in the solid waste stream is subject to regulation pursuant to Chapter 4 of Title 49, Arizona Revised Statutes. Where a source waste presents a specific risk to human health or the environment, regulations in addition to the general solid waste regulations are imposed.

Biohazardous medical waste can generally be described as medical waste from regulated generators which is either soaked with blood or which has come into contact with infectious agents capable of transmitting disease to humans. Non-biohazardous medical waste is medical waste which is neither blood-soaked nor has it come into contact with an infectious agent. An example of non-biohazardous medical waste is a paper cup or a tissue in a physician's office used in the treatment of a common cold.

A.R.S. § 49-761(D) requires that ADEQ adopt rules regarding the regulation of biohazardous medical waste. A.R.S. § 49-761(E) permits ADEQ to decide whether to impose additional regulatory requirements (beyond the solid waste requirements) upon non-biohazardous medical waste. ADEQ believes that non-biohazardous medical waste does not pose a risk significantly different to that of general solid waste and is adequately regulated under the existing solid waste regulations, with the exception of discarded drugs. For this reason, the proposed rule sets forth handling and treatment standards for biohazardous medical waste, and addresses the proper disposal of 1 category of non-biohazardous medical waste, discarded drugs.

Infectious disease transmission is a chain of 4 events: the presence of an infectious agent; a sufficient number of infectious agents to cause an infection; a host; and a portal of entry to the host, such as a break in the skin or an orifice. The purpose of the proposed rule is to set forth enforceable standards which, when met, break the chain of disease transmission.

3. Current regulation of medical waste in Arizona.

At the present time, ADEQ regulates medical waste as solid waste and the Department of Health Services governs medical waste through its regulation of hospital environmental services. When the proposed rules become effective, ADEQ will govern medical waste as a special category of solid waste. The state OSHA Bloodborne Pathogen Rule does not govern waste, although it regulates blood and blood products. There is some overlap of subject matter with the Bloodborne Pathogen Rule because ADEQ's proposed rule regulates blood and body fluids when they are discarded. A brief summary of Arizona medical waste regulation follows:

a.) Hospital medical waste in Arizona currently is regulated by the Department of Health Services (ADHS) rules R9-10-220 and R9-10-320 adopted in 1979, which set forth standards for hospital environmental services. These rules require that all potentially hazardous waste (commonly defined as waste from isolation rooms and materials contaminated with blood or body secretions) be sterilized by incineration or autoclaving, and taken to a landfill. Rural hospitals with only 1 autoclave are permitted to double bag the waste and dispose it at an ADEQ approved landfill, if the landfill operator is notified and the waste is immediately buried.

b.) ADHS statutes currently require clinical laboratories to be licensed. Specimens and other potentially infectious materials must be sterilized prior to disposal in an approved landfill, incinerated, or with proper permission, poured down a sanitary sewer.

c.) ADHS's statutory authority covers the licensing of health care institutions, and ADHS currently regulates what goes on inside the institution as a condition of receiving that licensing. Thus, ADEQ's proposed rule would regulate medical waste from the back door of an ADHS licensed facility to final disposal in a landfill. However, waste treated on-site at a facility currently regulated by ADHS and set out for disposal must meet the treatment requirements set forth in ADEQ's proposed rule. ADEQ's rationale for this requirement lies in the fact that the Legislature has spoken most recently and directly to ADEQ and has mandated it to promulgate regulations for the proper handling and disposal of biohazardous medical waste. A facility or entity which generates biohazardous waste and sets it out for collection must follow the proposed rule requirements for packaging, storage, transportation and treatment.

d.) There is no permit requirement under ADEQ's proposed rule for facilities which treat waste on-site but the rule requires that treatment standards be met. ADEQ's proposed rule governs treatment facilities which accept for treatment biohazardous medical waste generated off-site. There is an exception for health care facilities which accept exempt waste, such as home-generated medical sharps or discarded drugs. These accepting facilities (absent other regulatory requirements) do not become subject to facility plan approval under A.R.S. § 49-762. ADEQ's rationale for this exemption is to encourage community hospitals to accept and treat home-generated medical sharps and other biohazardous medical waste, thus reducing the volume of used medical sharps set out for residential solid waste collection.

e.) Within the broader solid waste stream, the Legislature singled out medical waste for special handling as noted above. ADEQ's authority to regulate biohazardous medical waste stems from this identification.

f.) ADEQ and 3 counties (Maricopa, Pima, and Pinal) enforce air quality standards by issuing permits to incinerators which treat medical, pathological, and animal waste.

4. Impact On Current Biohazardous Medical Waste Management.

ADEQ's proposed rule enlarges the universe of regulated medical waste from those hospitals currently regulated under the ADHS rules. The ADEQ proposed rule governs more people because it imposes requirements on generators, transporters and treaters, in addition to those hospital generators traditionally regulated by ADHS. Also, the proposed rule imposes requirements on generators to either treat waste on-site or follow proper waste management, because it regulates the waste stream after it leaves the facility. Thus, these rules impose additional requirements related to transportation and final disposition of regulated medical waste.

5. Federal DOT Regulations

ADEQ is aware of federal Department of Transportation regulations which may preempt state law regarding transportation of regulated medical waste. Arizona transporters of medical waste regulated by federal law have been subject to federal law prior to ADEQ's proposed rule and will continue to be so governed. For this reason, ADEQ's proposed rule does not address placarding or other subjects addressed in the federal law.

6. Licensing Time-frames and the Medical Waste Rules

Today's proposed rule governs 2 new licenses that require licensing time-frames analysis. State law requires the Department to identify all licenses it issues and then to establish application review times in rule for certain of these licenses as governed by the licensing time-frame statutes at A.R.S. §§ 41-1072 through 41-1079. The Department's approach towards compliance with its licensing time-frames requirements is to administer them within a separate rule to appear at 18 A.A.C. 1, Article 5. A notice of proposed rulemaking for the Department's licensing time-frame rule appeared in the October 23, 1998, edition of the *Arizona Administrative Register*. Once promulgated, the Department expects to amend the licensing time-frames rule at least annually to incorporate additions, deletions, and other changes. This means that licensing time-frames requirements for new licenses governed by today's proposed rule will appear in the next amendment to the licensing time-frames rule. The Department expects to propose the first amendment to the licensing time-frames rule during the 3rd quarter of 1999. An analysis of specific medical waste provisions and licensing time-frames follows.

R18-13-1409. The Department anticipates that it will issue this license, the transporter registration, within 7 calendar days, with the result that this provision will fall within the A.R.S. § 41-1073(D) exclusion from licensing time-frames.

R18-13-1410 through R18-13-1413. These sections govern a number of licenses issued by the Department and are similar in their structure and application requirements to other solid waste facility plan approvals. The Department anticipates that it will address the licensing time-frame requirements for these medical waste facility plan approvals in its next annual licensing time-frame amendments and that these time-frames will be similar to those already shown for the other solid waste facility plan approvals. These time-frames will be subject to a subsequent rulemaking, further program analysis and public comment.

R18-13-1414. The Department anticipates that the time-frames in this Section will be inserted into the next annual licensing time-frame amendments and will have an overall time-frame of approximately 45 days. These time-frames will be subject to a subsequent rulemaking, further program analysis and public comment.

B. Specific Section-by-Section Explanation of this Proposal:

1. Executive Summary of the Rule.

Under the proposed rule, the types of medical waste that are regulated are biohazardous medical waste and discarded drugs. Biohazardous medical waste is defined as cultures and stocks, waste human blood and blood products, pathological wastes, isolation waste, medical sharps, and research animal waste.

All regulated medical waste must be treated to a high level of disinfection. Some additional processing, packaging, or treatment are required for certain types of waste. For example: medical sharps are rendered incapable of puncturing; chemotherapy waste are incinerated or landfilled; human body parts are made unrecognizable; and cultures and stocks are sterilized.

Treatment can be accomplished by incineration, autoclaving, or any alternative treatment technology that complies with ADEQ standards for that type of waste. Providers of alternative treatment technologies will be required to register with ADEQ. The registration process will require laboratory proof that the technology complies with ADEQ standards.

Under the proposed rule, household generators of regulated medical waste are exempt. However, ADEQ is aware that home generated medical waste is 1 of the largest contributors to the medical waste stream. For this reason, ADEQ's Solid Waste Section (SWS) plans to take advantage of opportunities to educate the public about the risks posed by medical sharps and appropriate method(s) of disposal. Arizona Revised Statutes (A.R.S.) § 49-833 requires the Department to, "implement and conduct a program of public education and provide information to increase awareness of individual responsibility for properly disposing of solid waste..." This educational effort will take place outside the regulatory arena.

The proposed medical waste rule applies to regulated medical waste once it is placed out for collection and does not apply to the manner in which a generator collects, handles and stores the waste inside the generator's place of business.

Regulated medical waste is treated either on-site by the generator, shipped to an off-site treatment facility approved by ADEQ, or shipped to a public solid waste facility which accepts untreated medical waste. On-site treatment includes incineration, autoclaving, or any alternative treatment technology that complies with ADEQ standards for that type of waste. After on-site treatment, a generator must comply with some packaging requirements prior to placing the treated medical waste out for collection by a municipal solid waste collector. Labeling of medical waste treated on-site is required to indicate that the treatment standards have been met. A generator must keep treatment records for 6 months after treatment.

Generators who ship regulated medical waste to an off-site treatment facility or to a municipal solid waste landfill must properly package the waste prior to placing it out for collection. Proper packaging is a red plastic bag placed in either a reusable container or a cardboard box. Medical waste sharps are placed in a rigid container to prevent puncture, then placed inside the reusable container or a cardboard box. A generator must provide a secure storage area for the packaged regulated medical waste, until the waste is collected. If putrescible regulated waste is stored for longer than 7 days, refrigeration is required. Labeling of regulated

medical waste with the universal biohazard symbol is required. A generator may also use a mail back system for medical waste sharps.

Once a hauler accepts regulated medical waste from the generator, the waste becomes the property of the hauler. A medical waste hauler must be registered with ADEQ, and as part of the registration process, each collection vehicle must have a permit from the local county health department, where required, to demonstrate compliance with ADEQ vehicle standards. Each hauler must provide the generator with a written receipt (tracking form) showing that the waste has been accepted from the generator. This written receipt accompanies the waste until the waste is delivered to a treatment or disposal facility. The hauler is required to have a contingency plan to address spills.

All off-site storage, transfer, treatment or disposal facilities are required to obtain facility plan approval pursuant to ARS § 49-762. The same treatment standards apply to off-site and on-site treaters. After treatment, treated medical waste may be taken to a municipal solid waste landfill for disposal, or recycled.

2. The Section-by-Section explanation of these proposed rules is organized as follows:

R18-13-1401. Definitions

The proposed definition of regulated medical waste is consistent with Occupational Safety and Health Administration and other regulatory definitions in order to provide a common frame of reference for all persons who generate or come into contact with regulated medical waste. The 6 classes of regulated medical waste are: cultures and stocks of infectious agents and associated biologicals; waste human blood and blood products referring to discarded waste human blood and blood components, such as serum and plasma; pathological wastes removed during autopsy or other medical procedures; medical sharps including hypodermic needles, syringes, pasteur pipettes, glass contaminated with blood or speciums, and scalpel blades; research animal waste including contaminated animal carcasses, body parts and bedding of animals that were exposed to infectious agents; and isolation waste generated by humans isolated to protect others from highly virulent diseases.

R18-13-1402. Applicability

The medical waste stream begins at the point of generation and continues through handling until treatment or disposal. The proposed rule applies to any person who generates, stores, collects, transports, treats or disposes of regulated medical waste. ADEQ recognizes that Arizona Department of Health Services, not ADEQ, regulates activities inside a health care facility. For this reason, ADEQ regulation begins at the point the waste is set out for collection and disposal. Regulated medical waste set out for disposal must meet the standards set forth in rule. The rule applies to a person in physical possession of regulated medical waste which does not meet the treatment standards. Regulated medical waste treated as set forth in the proposed rule becomes solid waste and is handled in accordance with solid waste requirements.

R18-13-1403. Exemptions; Partial Exemptions

The proposed rule does not govern medical waste generated in a home environment whether by self-care or administered by others. The rule exempts discarded drugs and liquid and semi-liquid regulated medical wastes poured down a sanitary sewer if the operator of the waste water sewer system and treatment facility allows or otherwise approves of the discharges. An exemption is granted for unused medical sharps returned to the manufacturer via the U.S. Postal Service or private shipping agent. Human corpses, remains and anatomical parts that are intended for interment or cremation are exempt from regulation. However, if medical sharps are generated during preparation, the sharps must be disposed of as prescribed in rule.

The rule grants a partial exemption to a multi-use vehicle operated by health personnel when conducting routine business as long as the waste is properly packaged, secured to minimize spills, the vehicle is decontaminated when it shows signs of visible contamination, and regulated medical waste is transported to a treatment facility or a municipal solid waste landfill which accepts untreated medical waste. If these same requirements are met, a partial exemption is also granted to a person who transports regulated medical waste between multiple properties owned or operated by the same owner or governmental entity.

Health care facilities which accept exempt waste, such as home-generated medical sharps or discarded drugs, do not (absent other regulatory requirements) become subject to facility plan approval under A.R.S. § 49-762.

A generator who contracts with a permitted transporter to transport regulated medical waste to a medical waste treatment or disposal facility is relieved of any obligation to retrieve improperly disposed regulated medical waste once the transporter accepts possession. A generator who self-hauls to an approved medical waste facility is relieved of any obligation to retrieve medical waste that is improperly disposed, once the treater accepts possession.

The proposed rule does not govern nuclear material covered by the Atomic Energy Act of 1954 or hazardous waste covered by ADEQ's hazardous waste requirements.

R18-13-1404. Transition and Compliance Dates

The effective date of this Article is the date of publication in the *Arizona Administrative Register* of the notice of final rulemaking. Unless otherwise specified in rule, the date for compliance with this Article is the effective date of this Article. A person who provides alternative medical waste treatment technology in operation by a generator before the effective date of this Article must register the technology with the Department within 90 days after the effective date of this Article, after 90 days of the effective date of this Article, that person cannot not provide technology to additional generators until Departmental registration is received, and after Departmental registration is received, that person must provide to all generators using the technology a

copy of the registration certification and manufacturers specifications.

An on-site incinerator or on-site sterilization unit which is brought into operation on or after the effective date of this Article is subject to equipment specification requirements. An on-site alternative medical waste treatment unit in operation on the effective date of this Article must come into compliance with the equipment specification requirements within 180 days after the effective date of this Article.

A generator utilizing alternative medical waste treatment technology prior to the effective date of this Article shall obtain, within 180 days after the effective date of this Article, the Departmental registration number, and equipment specifications as described in R18-13-1414 from the technology provider. A generator who utilizes incineration or steam sterilization for on-site treatment of regulated medical waste before the effective date of this Article, may continue to do so after the effective date as long as the treatment requirements of R18-13-1415 and the on-site treatment requirements of R18-13-1405 are met.

A person who has transported before to the effective date of this Article must obtain Departmental registration within 90 days after the effective date of this Article. An operator of a medical waste transfer facility must obtain a solid waste facility plan within 180 days of the effective date of this Article. An operator of a medical waste treatment facility who has obtained Departmental plan approval to operate a medical waste treatment facility and who has obtained that approval before the effective date of this Article may continue to operate under that plan approval if certain conditions are met. If ADEQ determines that an updated solid waste facility plan is required, a treater must submit an updated plan within 180 days of receipt of the Department's determination. The treater may continue to operate under the conditions specified in rule while the Department reviews and determines whether to approve or deny the updated plan. After the effective date of this Article, solid waste facility plan approval as described in A.R.S. § 49-762.03 is required for a medical waste treatment or disposal facility prior to construction.

R18-13-1405. Regulated Medical Waste Treated On-Site

A person who treats regulated medical waste on-site must meet the treatment standards. Specific requirements are set forth for persons utilizing incineration, autoclaving, and alternative treatment methods including recognizable human body parts which are autoclaved, must be further processed. In addition, if requested by the solid waste collection agency or landfill, a person must provide certification that the treated solid waste meets the treatment standards. Finally, the treated waste must either be disposed of as a solid waste at a Department approved municipal solid waste landfill or recycled.

R18-13-1406. Regulated Medical Waste Transported Off-Site for Treatment

A generator must properly package the waste and provide a secure storage area for it until it is collected by a transporter or self hauled to a treatment or disposal facility. A generator must also obtain a tracking document for each waste load accepted by a transporter.

R18-13-1407. Packaging

A generator who sets regulated medical waste out for collection for off-site treatment or disposal must package the regulated medical waste in either a red disposable plastic bag which is then sealed and placed in a secondary container. Alternatively, a generator can package the waste in a reusable container or bag which meets certain specifications. Any container used for the storage or transport of regulated medical waste which is not capable of being decontaminated as described in rule is handled as regulated medical waste. A generator who disposes of regulated medical waste treated on-site must package the treated medical waste according to the waste collection agency's requirements. In addition, before placing the treated medical waste out for collection, a generator must attach a label to the container which bears the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards"

Encapsulation of regulated medical waste or medical sharps waste and subsequent disposal as solid waste is acceptable under this Article if the agent used to solidify and encase the contents meets the treatment standards. Medical sharps must be rendered incapable of being re-used. Medical sharps may then be sent to a Department approved medical waste facility, sent via a mail back system to a treatment facility, or disposed of in a landfill.

R18-13-1408. Storage

A generator may place a container of regulated medical waste alongside a container of solid waste if the regulated medical waste is not allowed to co-mingle with the solid waste. The storage area may be used for storage of solid waste and for medical waste, as long as the medical waste is easily identifiable and kept separate from the containers of solid waste. Beginning at the time the waste is set out for collection, a generator who stores regulated medical waste may keep putrescent (capable of decomposing) regulated medical waste unrefrigerated if it does not create a nuisance. Putrescent regulated medical waste may be kept longer than 7 days provided that it is refrigerated at 40° F or less. Storage of regulated medical waste for longer 90 days requires facility plan approval under A.R.S. § 49-762 and in compliance with the design and operational requirements described in R18-13-1412.

The storage area must be kept free of contamination, and the waste protected from contact with water, precipitation, wind, or animals. Spills must be handled by re-packaging the regulated medical waste, re-labeling the containers and decontaminating any soiled surface. Notwithstanding compliance with rule provisions, if odors become a problem, a person storing medical waste must minimize objectionable odors and off-site migration of odors. In the event that efforts fail to control the odors, ADEQ may require waste removal after 3 days or waste refrigeration.

R18-13-1409. Transportation

A person who transports medical waste must possess state-wide Department registration in addition to holding a permit, license, or approval where required by a local health department, environmental agency, or other governmental agency with jurisdiction. Department registration is obtained by providing ADEQ with the name, address and telephone number of the transportation company or entity. In addition, a person who transports regulated medical waste must maintain in the vehicle at all times a transportation management plan which includes routine procedures used to minimize the exposure to employees and the general public, and emergency procedures used for handling spills or accidents.

A transporter who accepts regulated medical waste from a generator must leave a copy of the tracking document with the person from whom the waste is accepted. A copy of the tracking document accompanies the person who has physical possession of the regulated medical waste. Upon delivery to a Department approved transfer station, storage facility, treatment or disposal facility, the transporter must obtain a signed copy of the tracking document signifying acceptance of the regulated medical waste.

A person who transports regulated medical waste in a vehicle dedicated to the transportation of regulated medical waste must ensure that the cargo compartment can be secured to limit access to authorized persons, and that the cargo compartment meets certain specifications including having a fully enclosed, leak-proof cargo compartment separate from the driver's compartment. In addition, there are requirements for a person who transports regulated medical waste in a vehicle not dedicated to the transportation of regulated medical waste, but which is used longer than 30 days in commerce.

A person who transports regulated medical waste is required to accept only properly packaged regulated medical waste, and regulated medical waste which is accompanied by a tracking form. A transporter is must deliver the waste to a Department-approved regulated medical waste storage, transfer, treatment facility, or a municipal solid waste landfill within 24 hours of collection or refrigerate the waste at 40° or less until delivery.

R18-13-1410. Storage, Transfer, Treatment and Disposal Facilities; Facility Plan Approval Requirement

A person must obtain solid waste facility plan approval from the Department as described in A.R.S. § 49-762 to construct any facility that will be used to store, transfer, treat or dispose of regulated medical waste that was generated off-site, and facility plan approval must be obtained before the start of construction of the medical waste treatment facility.

R18-13-1411. Storage and Transfer Facilities; Design and Operational Requirements

An operator of a storage facility or transfer facility must demonstrate compliance with all specified design and operation requirements, including where the regulated medical waste will be stored for longer than 24 hours, the facility must be equipped to refrigerate the regulated medical waste at 40° or lower. In addition, an operator may accept regulated medical waste only if it is accompanied by the tracking form, and must keep a copy of the tracking form documentation for 1 year. Where properly packaged medical waste is damaged or leaking, or the waste is improperly labeled or otherwise unacceptable, a transfer facility operator must reject the waste and return it to the generator, or alternatively, repackage the waste immediately and decontaminate the storage area.

R18-13-1412. Treatment Facilities; Design and Operational Requirements

An operator who applies for facility plan approval shall demonstrate compliance with documentation for the equipment specifications, and submit to the Department and have readily available at the facility, an operations procedure manual describing how the waste will be handled from the time it is accepted by the treater through the treatment process and final disposition of the treated waste. In addition, an operator may accept regulated medical waste only if it is accompanied by the tracking form, and keep a copy of the tracking form documentation for 1 year. Where properly packaged medical waste is damaged or leaking, or the waste is improperly labeled or otherwise unacceptable, a treatment facility operator shall reject the waste and return it to the generator. Alternatively, the facility operator may repackage the waste immediately and decontaminate the storage area.

An operator must demonstrate compliance with all specified design and operation requirements. Specified requirements if incineration technology is used include a provision that the facility operator must ensure that the incinerated medical waste is reduced to ash, and perform a waste determination of the ash to identify if the ash is hazardous. In addition, the facility operator must maintain record keeping of equipment maintenance and operational performance levels for 3 years, and make treatment records available for Departmental inspection upon request.

R18-13-1413. Changes to Approved Medical Waste Facility Plans

The proposed rule implements A.R.S. § 49-762.06 and requires that, before making any change to an approved facility plan, a treatment facility operator must submit a notice to the Department describing the category which is requested. The Department will then request further notice or action on the part of the operator, depending upon the extent of the change, with more extensive changes triggering more extensive regulatory requirements.

R18-13-1414. Alternative Medical Waste Treatment Methods; Registration and Equipment Specifications

A manufacturer or its agent who applies for alternative medical waste treatment method registration must submit to ADEQ information regarding the treatment method including the name and address of the manufacturer, description of the alternative medical waste treatment method, a list of any other states in which the treatment method is used, and a copy of any state approvals, a description of bi-products generated as result of the alternative treatment method, and written documentation which demonstrates that the alternative medical waste treatment method is capable of compliance with the treatment standards.

R18-13-1415. Treatment Standards; Quantification of Microbial Inactivation and Efficacy Testing Protocols

A. Treatment standards. In Arizona, incineration and autoclaving (steam sterilizing) have been the traditional methods of treating medical waste. For this reason, all other treatment methods are considered alternative treatment technologies. In exploring the various treatment technologies and to determine an appropriate treatment standard, the ADEQ consulted the "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" (Treatment Manual), prepared by the State and Territorial Association on Alternate Treatment Technologies (April, 1994). The Treatment Manual has been used by several other states in determining regulatory treatment standards, and ADEQ discussed its use of the Treatment Manual with stakeholders at the 1994 and 1995 roundtables.

As noted earlier, stakeholders at these roundtables advised ADEQ that they were unable to come forth with recommended treatment standards because of the varying capabilities of competing technologies and market share interests. For example, incineration and autoclaving achieve sterilization while several other technologies, such as microwaving, do not.

The Treatment Manual describes a range of treatment levels from sterilization (Level IV); high disinfection (Level III); intermediate disinfection (Level II) to low disinfection (Level I).

The proposed rule sets forth Level III as the standard for all waste categories except cultures and stocks and chemotherapy waste. In choosing this standard, the ADEQ considered the arguments set forth in the Treatment Manual and its recommendation that Level III be required of all emerging medical waste technologies. ADEQ intended to create a regulatory scheme flexible enough to allow generators to make economic decisions appropriate to their needs. One way of creating this flexibility is to allow emerging medical waste treatment technologies which meet the treatment standards entry into the Arizona market. This allows market forces to resolve the access to treatment and disproportionate cost issues faced by rural generators and small generators.

Under the proposed rule, regulated medical waste treated to achieve a Level III classification is regulated as solid waste. A Level III classification is defined as inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of *B. stearothermophilus* spores or *B. subtilis* spores at 4 Log_{10} reduction or greater.

B. Indicators of treatment efficacy. The proposed rule sets forth representative biological indicators which demonstrate that treatment efficacy has been achieved. In addition, it sets forth the method by which microbial inactivation is quantified, and also provides an alternative quantitative measurement of microbial inactivation. Acceptable demonstration of compliance includes demonstration submitted from an independent testing laboratory.

C. Manufacturer's specifications are followed. Under the proposed rule, ADEQ does not approve medical waste treatment technologies. Where a manufacturer states that a given technology is suitable for a given classification of waste, ADEQ will accept treatment which follows the manufacturer's specifications as long as Level III treatment is achieved. Thus, it will accept a manufacturer's determination that the type of waste (one of the 6 classes described above) is appropriate for a given treatment technology.

D. Special treatment for certain categories. Cultures and stocks are required to be sterilized, and chemotherapy waste must be incinerated or disposed of in an approved hazardous waste disposal facility.

E. Encapsulation, grinding and compaction are not considered treatment. The proposed rule requires that encapsulated regulated medical waste is treated before encapsulation, or the encapsulating material itself achieve Level III treatment. Medical sharps are to be treated in 1 of 3 ways: 1.) sending to a Department approved medical waste treatment facility; 2.) properly packaged, utilizing a mail back system; 3.) rendering the medical sharps incapable of being reused, and utilizing an encapsulation agent which meets the treatment standards. ADEQ considers "incapable of being reused" as incapable of being used for their original purpose.

R18-13-1416. Recycled Materials

The proposed rule permits recycling as long as certain conditions are met. Regulated medical waste intended for recycling must be placed in a red bag and shall not be removed until treated. Medical medical waste intended for recycling is to be treated before being sent for recycling, or be sent straight to a treatment facility, then recycled.

R18-13-1417. Disposal Facilities; Operational Requirements

A municipal solid waste landfill may accept untreated regulated medical waste if the operator has received facility plan approval under A.R.S. § 49-762 for this activity and follows best management practices. Those best management practices include: only accepting properly packaged regulated medical waste; keeping the disposal area separate from the general disposal area; covering the deposited medical waste with soil before compaction; labeling the disposal area; covering the regulated untreated medical waste with 6 inches of compacted soil; and prohibiting salvaging of untreated medical waste.

6. **A reference to any study that the agency proposes to rely on in its evaluation of or justification for the proposed rule and where he public may obtain or review the study, all data underlying each study, any analysis of the study and other supporting material:**

The Department has utilized the following studies in this rulemaking: "Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies" (Treatment Manual), prepared by the State and Territorial Association on Alternate Treatment Technologies (April, 1994); Arizona Department of Environmental Quality 1995 Generator Study"; U.S.

Department of Commerce, Bureau of the Census, County Business Patterns 1989 and 1992 Arizona; Arizona State Veterinary Medical Examining Board (computer printout dated 2/23/95); Arizona Department of Health Services, Office of Lab Licensure and Certification (Oscar Report 86 dated 5/11/95); Arizona State Board of Dental Examiners (copy of labels, no date); Arizona State Board of Funeral Directors and Embalmers (crematory list dated 2/03/95 and establishment list, date printed 2/23/95); Arizona Hospital and Health care Association (labels, no date); Arizona Medical Association (purchased labels from a computer generated random sample); Arizona Department of Health Services, Health and Child Care Review Services, Health Care Licensure, Medical Facilities Section (Medicare certified/state licensed outpatient treatment clinics dated 6/02/95, Medicare certified/state licensed ambulatory surgical centers and state licensed outpatient surgical centers dated 3/01/93, Medicare certified comprehensive outpatient rehabilitation facilities dated 3/04/94, state licensed infirmaries dated 6/02/94, Medicare certified/state licensed rural health clinics dated 6/02/95, state licensed recovery care centers dated 2/01/94, licensed residential care institutions dated 6/02/95, Medicare certified/state licensed nursing care institutions dated 5/04/93, licensed adult day health care facilities dated 4/03/95, licensed supervisory care homes dated 5/04/93, licensed adult care homes dated 6/02/95, licensed respite unclassified facilities dated 4/03/95, and state licensed unclassified health care institutions dated 11/01/94). These materials are available for review at ADEQ at 3033 North Central Avenue, Phoenix, Arizona, 85012.

7. **A showing of good cause why the rule is necessary to promote a state interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**
Not applicable.

8. **The preliminary summary of the economic, small business and consumer impact:**
OVERVIEW

1. Introduction

The proposed rulemaking, upon which the preliminary economic, small business and consumer impact statement (EIS) was developed, is identified as 18 A.A.C. 13, Medical Waste (new).

This section summarizes the incremental impacts expected as a result of promulgating this rule. The expression "incremental impacts" means probable costs and benefits that would occur as a result of this rule becoming effective, compared to the costs and benefits in the absence of this proposed rule. For example, past expenditures, and any future ones that would be incurred regardless of this rule, would not be considered incremental costs.

Research findings of this EIS are a result of numerous data-gathering activities that were conducted in 1995. Today's EIS is a continuation of that original research, updated to reflect recent policy decisions, notably that the rule does not govern medical waste generated in the home, and that it now permits landfills to accept untreated medical waste under certain conditions.

ADEQ is aware that recent market share changes in the Arizona medical waste treatment industry have occurred within the past year. As generators become more familiar with these changes, and to the extent that these changes alter treatment costs, ADEQ solicits this additional information for inclusion in the final EIS.

As a result of its research findings, ADEQ reached 3 conclusions:

1.) Overall impacts on all regulated parties should be minimal.

2.) Compliance costs mainly should consist of treatment costs for generators currently not treating their regulated medical waste.

3.) Environmental and public health benefits should accrue from improved management of Arizona's regulated medical waste.

This rulemaking has relatively low compliance costs because generators (medical service providers) significantly have increased the extent to which they treat regulated medical waste even in the absence of a regulatory program. In fact, many people believe that this rule is already in effect because ADEQ has previously proposed it.

2. Need for Rule

ADEQ believes that over the last several years the proportion of generators that treat their biohazardous ("regulated") medical waste has been increasing. If a generator survey had been undertaken in 1992, it likely would have shown a treatment rate significantly less than what was discovered in 1995. Likewise, if a survey had been done in 1998, it probably would have revealed a continuation of this trend. Numerous factors have contributed to a high-treatment rate among Arizona's generators (see A.4 below).

Even though there is a significant trend toward treatment, there still is a proportion of generators that currently are not treating their regulated medical waste. On almost a daily basis, the ADEQ receives telephone calls about improperly disposed of medical waste. Therefore, this rule is necessary to eliminate "problematic exposures" of medical waste. This rule provides ADEQ with more specifics with respect to improperly handled medical waste. More importantly, it assures the trend toward proper handling of medical waste by prescribing treatment of medical waste or the imposition of specific management practices for the disposal of untreated medical waste.

There is also a need for this rule from an environmental and public health perspective. The improper management of medical waste creates a potential for the spread of communicable diseases, such as human immunodeficiency virus (HIV) and hepatitis B. Furthermore, the need for this rule is intrinsically linked to anticipated benefits (see A.5. below). Although the majority of compliance costs already have been incurred through voluntary compliance by the generators, corresponding benefits have been

realized in anticipation of this rule. However, there still are costs to be incurred and benefits yet to be realized as a result of implementing this rule. Thus, the focus of this EIS is on the small proportion of generators currently not treating their regulated medical waste.

3. Entities Impacted

This rule is expected to impact the following entities: generators, treaters, transporters, medical waste handlers (e.g., refuse haulers and landfill personnel), landfill owners and operators, ADEQ and the public at large. The public at large includes private citizens, consumers of health-care services, and some medical waste handlers that may come into contact with medical waste during their daily work. The universe of generators includes 2 groups: hospital generators and non-hospital generators. Non-hospital generators comprise 6 categories: physicians' offices and clinics; dentists' offices; nursing and long-term care facilities; veterinarians; funeral homes/crematories; and laboratories. These groups also include a small proportion of public generators (e.g., county jails, health departments, clinics, and hospitals). Based on survey findings, these public generators (government owned or operated) are expected to be impacted in the same manner as the private generators. Table 1 summarizes the findings of the generator survey.

Treaters include commercial facilities, for example, that incinerate, autoclave, or microwave regulated medical waste. Treaters also include companies which sell mail-back kits that dentists' offices and other small quantity generators can use to dispose of regulated medical waste. Their waste predominately is comprised of medical sharps, which can be mailed-back in containers for subsequent treatment and disposal.

4. Factors Contributing to Minimal Impacts

The overall impacts of this rule are minimal because of several factors. These factors have acted as a catalyst for generators to treat their regulated medical waste even in the absence of a state environmental regulatory program. The ADEQ discovered that regulated medical waste is being treated at an overall rate greater than otherwise might be expected. Factors that have contributed to a high-treatment rate are summarized below:

a. National attention has been focused on the management of medical waste, beginning a decade ago when medical waste appeared on beaches and in other public places.

b. The Medical Waste Tracking Act of 1988, a 2 year demonstration program to track medical waste in certain eastern states (1989-1991), was implemented by the EPA. Additionally, the Agency for Toxic Substances and Disease Registry, U.S. Public Health Service, has been mandated by Congress to prepare a report on the health effects of medical waste.

c. The regulated industry and public have anticipated since 1992 that the ADEQ would promulgate regulated medical waste rules.

d. The Arizona Department of Health Services has promulgated rules which require Arizona's hospitals to treat potentially hazardous medical waste (1979).

e. Most municipal solid waste landfills in Arizona have refused to accept untreated regulated medical waste.

f. The federal Occupational Safety and Health administration (OSHA) has promulgated occupational exposure standards to protect worker health and safety.

g. The EPA Office of Technology Assessment has published a guide for the management of infectious medical wastes (1986).

h. The Center for Disease Control has published several medical waste management documents on hospital waste (1983, 1985, 1987, and 1988).

i. National professional associations, commissions, and societies have advanced various guidelines for the healthcare industry (e.g., American Hospital Association and Joint Commission on Accreditation of Healthcare Organizations).

j. Many generators have considered the potential liability for untreated or improperly disposed of regulated medical waste.

k. Arizona treaters aggressively have marketed their services to all categories of generators and convinced many that they need to have their regulated medical waste treated.

5. Rule Benefits

Benefits are expected to accrue to generators and to the public at large. Because of the public's concern about the proper disposal of medical waste and the fear (both real and imagined) of communicable diseases and infectious agents, improved management of medical waste should have wide-spread impacts. For example, reducing the potential exposure to untreated, or otherwise improperly managed regulated medical waste, is expected to lessen the probability of occurrence of injury, infection, or disease. Likewise, improved management of regulated medical waste is expected to reduce the potential for environmental degradation. From an occupational standpoint, it could mean less contact with potentially hazardous regulated medical waste for some medical waste handlers (e.g., waste haulers and landfill personnel).

Other possible benefits from the improved management of medical waste could include the following: (1) Reduced incidents of improper disposal of regulated medical waste by generators; (2) Improved handling and less careless behavior by some health-care workers, waste haulers, and landfill personnel; (3) Reduced waste from generators by improved source separation of non-regulated medical waste (not over classifying regulated medical waste); (4) Less regulatory uncertainty and improved awareness

by all affected parties; and (5) Improved professional image. This last potential benefit could be more important than one might expect because the public generally has an aversion to discarded medical sharps, body parts, body fluids, and used bandages.

The regulatory cost of this rule is the cost to properly manage regulated medical waste to reduce the potential spread of infection. The ADEQ expects this cost to be borne by all entities responsible for generating regulated medical waste. Under this rule, generators have flexibility in making treatment decisions that are economically sensible because the ADEQ does not mandate a specific treatment methodology, but instead sets forth specified treatment standards that must be met. This approach allows alternative treatment methodologies which meet the specified standard to enter the Arizona market, thus creating more numerous treatment options for generators. In addition, the ADEQ will allow untreated medical waste to be landfilled provided that the landfill owner/operator accepts such waste and complies with best management practices. In this way, a generator has greater flexibility to make economically sound decisions appropriate to his or her situation.

This rule will also ensure that generators who currently treat their waste on a voluntary basis continue to do so, and comply with other rule provisions. Generators who are not presently treating their regulated medical waste will be expected to begin treating and to comply with all rule provisions. Without this rule, there is no requirement to properly manage regulated medical waste. As a result of anticipated benefits, the ADEQ expects probable benefits to outweigh probable costs.

B. RESEARCH FINDINGS

1. Data-Gathering Activities

The primary data source is a generator survey conducted mid-year 1995. A stratified, random sample methodology was used to reduce sampling bias and to improve the reliability and validity of the survey. The ADEQ mailed surveys to more than 1,000 generators out of an estimated universe of nearly 7,300 generators. The overall sample size was relatively small at 3.7 percent. Other data sources include conversations with treaters, pharmacies, state associations (e.g., Arizona Hospital and Healthcare Association and Arizona Dental Association), companies which sell mail-back kits for sharps disposal, and a company which sells a system to encapsulate sharps.

In September of 1995, the ADEQ sent a treater survey to 4 treaters and 2 transporters who had established businesses in the state, as well as 1 treater located in New Mexico that transports waste out of Arizona. None of the treaters or transporters responded to the survey. However, since this survey was conducted, the market has changed due to business acquisitions. Currently 2 treaters are operating in Arizona.

2. Generator Treatment Rate

The ADEQ concluded from the generator survey that about 95% of Arizona's generators currently are treating their regulated medical waste. This treatment rate includes generators transferring their regulated medical waste to another division or generator, presumably for treatment. This high treatment rate may be overstated because of sampling errors, non-response bias, and other factors.

Treatment may be performed either on-site or off-site. Generators which perform on-site treatment must meet the rule standards for treatment efficacy or transfer to an off-site facility which meets these standards. Some generators may use their own treatment devices on-site, such as an autoclave. Other generators may use off-site treatment, that is, regulated medical waste is transferred to a commercial treatment facility (treater). A proportion of small quantity generators that predominantly produce medical sharps may purchase mail-back kits, which represent another option of off-site treatment previously mentioned.

3. Cost to Generators Not Treating

If 95 percent of the generators currently are treating, the remaining 5 percent which have chosen not to treat their regulated medical waste, will bear the incremental costs of treating. The annual compliance cost for these generators is estimated at $350,000. However, because of the small sample size and other factors, the compliance cost for generators not treating may be more than the amount inferred from the generator survey data.

The cost to individual generators not treating will vary according to the amount of regulated medical waste they produce and to the category of generator they belong. Average treatment costs are a result of 4 factors: (1) Quantity of regulated medical waste produced, (2) Pickup schedule, (3) Number of containers to be picked up, and (4) Distance from the treater (in some cases). For example, dentists' offices, which only produce a monthly average of 4 pounds, are expected to pay an average amount of $420 annually. In contrast, physicians' offices and clinics are expected to pay $1,920 annually, or almost five times that amount. For further cost details and other survey findings, refer to Table 1.

It is evident from Table 1 that dentists' offices generate the least amount of regulated medical waste. In fact, their average is 32 times less than the amount produced by physicians' offices and clinics. The impact of this rule upon dentists' offices, and other small quantity generators, may be the greatest on a per pound basis. This phenomenon is directly related to the industry's pricing scheme and the small quantity of regulated medical waste produced. Treatment costs, for instance, expressed as equivalent costs per pound, range from a high of $19.81 for dentists' offices to a low of 67¢ for hospitals.

Except for hospitals, and other large quantity generators that can negotiate off-site treatment on a per pound basis, most non-hospital generators pay a per container charge for pickup to have their regulated medical waste treated off-site. Furthermore, some generators may pay a transportation surcharge if the treater, or a third party transporter, must transport their regulated medical waste a long distance to their treatment facility.

4. Other Costs

In addition to treatment costs, generators may experience other compliance costs, although unquantified, associated with the handling of regulated medical waste. These costs could include a combination of both one-time costs and annual expenditures for meeting packaging, storing, securing and recordkeeping requirements. Likewise, other entities affected by this rule could experience increased compliance costs. Examples of these costs include developing transportation management plans, registering alternative technologies, changing approved facility plans, and plan reviews for landfills opting to accept untreated regulated medical waste. Additionally, the ADEQ expects these compliance costs to be very minimal, such as the cost for generators treating on-site to label their treated waste and the cost for transporters to register with the ADEQ. It is ADEQ's understanding that some counties are already requiring transporters to be registered, and this same information could be sent to the ADEQ for registering these transporters.

C. COST-EFFECTIVE ALTERNATIVES

This rule does not mandate a specific treatment methodology. Moreover, the proposed rule allows new alternative treatment technologies to enter the Arizona market. Therefore, generators can choose the best treatment options for their business. This would include both on-site and off-site treatment options. For some generators, 1 option for reducing business costs may be to segregate non-regulated medical waste from regulated medical waste. Increased market competition in the future, as well as allowing untreated regulated medical waste to be landfilled, may help to reduce costs for some of these generators and to help maintain a market equilibrium for others.

For some small quantity generators, the mail-back kit, or an on-site system that encapsulates medical sharps, may be the most economical method of treating regulated medical waste. For other generators, it may mean fewer pickups by a treater, or a combination of fewer pickups and purchasing larger containers. It may also mean some generators will have to construct a larger storage area or purchase a refrigeration unit. For yet other generators, it may mean purchasing an autoclave, or another comparable type of equipment to treat their regulated medical waste. Finally, for other generators, a cost-effective alternative may be to use equipment already on-site to treat their regulated medical waste. For example, the autoclave could serve a dual purpose for sterilizing medical instruments and supplies and for treating regulated medical waste. For generators that decide to purchase a benchtop autoclave, the cost will range from $1,500 to $5,000. Even if the economic impacts of this rule on generators are relatively minimal, any increased costs of doing business by the generators probably will be passed on to consumers of health care services.

Although it is expected that most generators will have their regulated medical waste treated off-site, some will treat on-site. A 3rd option allowed in the rule is for generators to send untreated regulated medical waste to a landfill for disposal. However, each landfill owner/operator who agrees to accept untreated regulated medical waste must follow specified best management practices (BMPs). As a direct result of landfills following these BMPs, the ADEQ expects disposal costs may increase for generators choosing this disposal method. However, costs expected to be passed on to the generator are anticipated to be relatively minimal, and perhaps equal to or less than what many generators pay to have their waste hauled off site and treated. Generators now are able make a business decision by comparing the cost of treatment to the cost of landfilling. This my be true particularly for generators located in rural areas of the state.

Increased costs for landfills accepting untreated regulated medical waste are expected to be a result of the following requirements: (1) Separate the disposal area from the general purpose area; (2) Post signs identifying the area; (3) Prohibit salvaging in the area; and (4) Apply a sufficiently thick cover over the waste so that compaction equipment will not come into contact with the untreated waste. In addition, a landfill will have to amend its plan in order to accept untreated waste. Plan review costs could range from a few hundred dollars to $20,000 with the average cost to review most plans at the low end of this range. Although all of these costs are expected to be passed on to generators opting for this disposal method, ADEQ cannot quantify them at this time.

D. Small Business Impact Reduction

A.R.S. § 41-1035 requires agencies implementing rules to reduce the impacts on small businesses by using certain methods where legal and feasible. Methods that may be used include the following: (1) Exempt them from any or all rule requirements, (2) Establish performance standards which would replace any design or operational standards, or (3) Institute reduced compliance or reporting requirements. The latter method could be accomplished by establishing less stringent requirements, consolidating or simplifying them, or by setting less stringent schedules or deadlines.

The ADEQ staff has evaluated these methods and determined that it has used performance standards in this rule to extent feasible or legal. ADEQ also concludes that it has reduced compliance and reporting requirements for all entities affected by this rule to the extent feasible or legal. However, the question of exemption requires a special note. When this rule originally was proposed in 1993, it contained a provision for exempting small quantity generators (producing < 600 pounds annually) from treating their medical waste. Although this provision was legal and feasible, it was met with intense opposition. Much of the argument against this option was loss of market share by the treaters and landfilling untreated medical waste by many public landfill operators, as well as others who argued that all medical waste should be treated. As a direct result of this opposition, the ADEQ withdrew the proposed rule.

Although as many as 80 percent of generators would be classified as small businesses, according to inferences made from the 1995 generator survey, certainly not all of these generators would qualify for an exemption. The ADEQ learned that its 1993 proposed option was not the preferred option by stakeholders. With this 1998 proposed rule, another option has been chosen

which provides flexibility and also a means of reducing the impact on many small businesses. This flexibility should provide maximum flexibility for both small and large generators.

The provisions of today's rule should provide options that allow generators to make treatment decisions that are the most cost effective and least burdensome. For example, generators can treat their regulated medical waste either on or off-site. A third option allows generators to landfill untreated regulated medical waste, provided the landfill accepts this waste stream and follows best management practices. This option especially was intended for those small generators located in rural areas that may not have access to commercial treaters at competitive prices.

E. REQUEST FOR DATA

Table 1 contains a summary of findings from the 1995 generator survey. If you would like to comment on these findings or obtain a copy of the preliminary EIS from the Department, please contact David Lillie. The preliminary EIS contains an explanation of survey findings, methodology, reliability, and assumptions. The Department will review and evaluate all comments and data received prior to completing the final EIS.

Table 1 Hospital and Non-hospital Regulated Medical Waste Generators: Summary of Survey Findings, 1995

Category of Generator a/	Estimated Number of Facilities b/	Estimated Sample Size (percent)	Average Amount of Waste (lbs. per mo.) c/	Medical Sharps (percent of waste)	Average Cost to Treat (dollars per month)	Average Cost to Treat ($ per pound) d/
Hospitals	110	44.5	12,298	18	2,590	.67
Physicians	4,185	2.8	128	43	160	4.79
Dentists	1,632	1.9	4	65	35	19.81
Nursing	571	4.4	61	40	88	6.05
Vets	362	1.4	56	61	43	1.89
Funeral	156	15.0	101	1	146	1.98
Laboratories	140	5.0	299	21	147	1.24

Source: Number of facilities by generator category were derived from state data bases and data from the U.S. Department of Commerce.

a/ The universe of generators includes two groups: hospital generators and non-hospital generators. Non-hospital generators include the following: physicians' offices and clinics, dentists' offices, nursing and long-term care facilities, veterinarians, funeral homes/crematories, and laboratories.

b/ Nearly 80 percent of the generators would be classified as small businesses according to survey inferences.

c/ These generators produce an estimated 22.2 million pounds of regulated medical waste annually. Hospitals produce two-thirds of this amount, or 14.7 million pounds; non-hospital generators produce the remaining 7.5 million pounds.

d./ Data represent unweighted averages.

9. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business and consumer impact statement:**

Name: David Lillie or Martha Seaman

Address: 3033 North Central Avenue, Eighth Floor
Phoenix, Arizona 85012-2809

Telephone: (602) 207-4436 or (800) 234-5677 ext. 4436 (Arizona only)

Fax: (602) 207-2251

10. **The time, place and nature of the proceedings for the adoption, amendment or repeal of the rule, or, if no proceeding is scheduled, where, when and how persons may request an oral proceeding on the proposed rule:**

The Arizona Department of Environmental Quality (ADEQ) will close the rulemaking record on January 8, 1999, and will include in the record all written comments received by 5 p.m on that date addressed to the Department at 3033 North Central Avenue, Phoenix, Arizona, 85012. The ADEQ will also include in the rulemaking record all written comments postmarked no later than January 8, 1999, and addressed to the Department at 3033 North Central Avenue, Phoenix, Arizona, 85012.

ADEQ will hold oral proceedings to receive public comments in accordance with A.R.S. § 41-1023. The time, place, and locations are listed below:

Date: January 4, 1999

Time:	Noon - 2:30 p.m.
Location:	Flagstaff City Council Chambers 211 West Aspen Avenue Flagstaff, Arizona
Date:	January 6, 1999
Time:	1 - 4 p.m.
Location:	Arizona State Office Building, Room 158 400 West Congress Tucson, Arizona
Date:	January 8, 1999
Time:	1 - 4 p.m.
Location:	Room 1706 (ADEQ Public Meeting Room) 3303 North Central Avenue Phoenix, Arizona

ADEQ is committed to complying with the Americans with Disabilities Act. If any person with a disability needs any type of accommodation, please contact ADEQ at least 72 hours before the hearing.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:
N/A

12. Incorporation by reference and their location in the rules:
29 CFR 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1997) is incorporated by reference in this rule in R18-13-1401(49). A reference to this incorporation also appears in R18-13-1407. Copies of the incorporated material are available for inspection at the Department of Environmental Quality and the Office of the Secretary of State.

13. The full text of the rules follows:

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 13. DEPARTMENT OF ENVIRONMENTAL QUALITY
SOLID WASTE MANAGEMENT

ARTICLE 14. MEDICAL WASTE

Section

ARTICLE 14. MEDICAL WASTE

R18-13-1401. Definitions

In addition to the definitions in A.R.S. § 49-701, the following definitions apply in this Article:

1. "Administrative consent order," for the purposes of this Article, means a bilateral agreement between the consenting party and the Department. A bilateral agreement is not subject to administrative appeal.
2. "Alternative treatment technology" means a treatment method other than autoclaving or incineration.
3. "Approved medical waste facility plan" means the document that has been approved by the Department under A.R.S. § 49-762, and that authorizes the operator to accept regulated medical waste at its solid waste facility.
4. "Autoclaving," or steam sterilization, means the act or process of achieving complete elimination or destruction of all forms of microbial life.
5. "Biohazardous medical waste" or "regulated medical waste" means that component of medical waste as defined in A.R.S. § 49-701 that is likely to transmit etiologic agent and is composed of 1 or more of the following:
   a. Cultures and stocks: Cultures and stocks of infectious agents and associated biologicals including cultures from medical and pathological laboratories, cultures and stock of infectious agents from research and industrial laboratories, waste from the production of biologicals, discarded live and atten-

uated vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures.

b. Waste human blood and blood products: Discarded waste human blood and blood products, and material containing free-flowing blood and blood components.

c. Pathological wastes: Human pathological wastes, including tissues, organs, body parts and body fluids that are removed during surgery or autopsy or other medical procedures, and specimens of body fluids and their containers.

d. Medical sharps: Discarded sharps, whether used or unused, in animal or human patient care or treatment or in medical research or industrial laboratories, including hypodermic needles, syringes, Pasteur pipettes, glass contaminated with blood or specimen, and scalpel blades.

e. Research animal wastes: Animal carcasses, body parts and bedding of animals that, during the research and production of biologicals, or testing of pharmaceuticals, are exposed to or contaminated by infectious agents that are pathogenic to healthy humans.

f. Isolation wastes: Biohazardous medical wastes containing discarded materials contaminated with blood, excretion, or exudates, or secretions from humans who are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or isolated animals known to be infected with diseases that are highly communicable to humans.

6. "Biologicals" means preparations made from living organisms or their products, including vaccines, cultures, or other biological products intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining to these activities.

7. "Biological indicator" means a representative microorganism used to evaluate treatment efficacy.

8. "Blood and blood products" means discarded human blood and any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products.

9. "Body fluids" means any substance that emanates or derives from the human body including: tissue, semen, vaginal secretions, cerebro-spinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Feces, nasal secretions, sputum, sweat, tears, urine, or vomitus are "body fluids" for the purposes of this Article only if they contain visible blood.

10. "C.F.R." means the Code of Federal Regulations.

11. "Chemotherapy waste" means any discarded material that has come in contact with an agent that kills or prevents the reproduction of malignant cells.

12. "Collection" means the pick-up of regulated medical waste from the generator's waste accumulation or storage area by a transporter for the purpose of transport the waste away from the generator's facility to a Department approved medical waste storage, treatment or disposal facility. Collection does not include waste pick-up by a janitorial service that occurs within the generator's place of business, if the waste is not removed from the generator's place of business.

13. "Contaminate" or "contamination" means to soil, stain or infect by the transfer of blood or other matter that may contain infectious agents.

14. "Decontaminate" or "decontamination" means the process of reducing or eliminating the presence of infectious substances, in order to reduce the likelihood of disease transmission from those substances by exposure to hot water of at least 180° F. for a minimum of 15 seconds, or by exposure to mixture of cold water and a disinfectant.

15. "Dedicated vehicle" means a motor vehicle or trailer that is pulled by a motor vehicle and that is used by a transporter for the sole purpose of transporting regulated medical waste.

16. "Discarded drug" means any prescription medicine, over-the-counter medicine, or controlled substance used in the diagnosis, treatment, or immunization of a human being or animal, that the generator intends to dispose. The term does not include hazardous waste or controlled substances regulated by the United States Drug Enforcement Agency.

17. "Disposal facility" means a municipal solid waste landfill that has been approved by the Department under A.R.S. § 49-762 to accept untreated regulated medical waste for disposal.

18. "Facility plan" has the meaning given to it in A.R.S. § 49-701.

19. "Free flowing" means any liquid which separates readily from any portion of a regulated medical waste under ambient temperature and pressure.

20. "Generator" means a person whose act or process produces regulated medical waste or whose act 1st causes a regulated medical waste to become subject to regulation.

21. "Hard-plastic or metal container" means a "medical sharps container" as defined below or a heavy plastic container such as liquid detergent bottle that has a screw on lid or a tightly secured lid.

22. "Hazardous waste" has the meaning prescribed in A.R.S. § 49-921(5).

23. "Improper disposal of regulated medical waste" means the disposal by a person of untreated or inadequately treated regulated medical waste at any place that is not approved to accept untreated regulated medical waste.

24. "Independent testing laboratory" means a testing laboratory independent of oversight activities by a provider of alternative treatment technology.

25. "Infectious agent" means a type of microorganism, bacteria, mold, parasite, or virus that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

26. "Medical sharps container" means a vessel that is rigid, puncture resistant, leak proof, and equipped with a locking cap.

27. "Medical sharps waste" means any medical device having acute rigid corners, edges, or protuberances capable of cutting or piercing, including but not limited to, all of the following:

a. Hypodermic needles, hypodermic needles with syringes, blades, needles with attached tubing, syringes contaminated with biohazardous waste, acupuncture needles, and root canal files.

b. Broken glass items, such as Pasteur pipettes and blood vials contaminated with regulated medical waste.

28. "Medical waste," as defined in A.R.S. § 49-701, means "any solid waste which is generated in the diagnosis, treatment or immunization of a human being or animal or in any research relating to that diagnosis, treatment or immunization, or in the production or testing of biologicals, and includes discarded drugs but does not include hazardous waste as defined in A.R.S. § 49-921 other than conditionally exempt small quantity generator waste."
29. "Medical waste treatment facility" or "treatment facility" means a solid waste facility approved by the Department under A.R.S. § 49-762 to accept and treat regulated medical waste from off-site generators.
30. "Multi-purpose vehicle" means a car, van or truck operated by a public health public worker, the general purpose for which is the non-commercial transporting of people and hauling goods and supplies, but not solid waste. A multi-purpose vehicle is limited to hauling regulated medical waste generated off-site by public health workers in providing services.
31. "Off-site" means a location that does not fall within the definition of "on-site" described in A.R.S. § 49-701(23).
32. "Packaging" or "properly packaged" means the use of a container or a practice under R18-13-1407.
33. "Putrescible waste" means waste materials capable of being decomposed rapidly by microorganisms.
34. "Radioactive material" has the meaning under A.R.S. § 30-651.
35. "Regulated medical waste" means biohazardous medical waste, medical sharps waste, and discarded drugs.
36. "Secure" means to lock out or otherwise restrict access to unauthorized personnel.
37. "Spill" means either of the following:
    a. Any release of regulated medical waste from its package while in the generator's storage area.
    b. Any release of regulated medical waste from its package or the release of packaged regulated medical waste by the transporter at a place or site that is not a medical waste treatment or disposal facility.
38. "Sterilization" means the complete elimination or destruction of all forms of microbial life.
39. "Store" or "storage" means, in addition to the meaning under A.R.S. 49-701, either of the following:
    a. The temporary holding of properly packaged regulated medical waste by a generator in a designated accumulation area awaiting collection by a transporter.
    b. The temporary holding of properly packaged regulated medical waste by a transporter or a treater at an approved medical waste storage facility or treatment facility.
40. "Technology provider" means a corporation that manufactures, or a vendor who supplies alternative medical waste treatment technology.
41. "Tracking document" means the written instrument which signifies acceptance of regulated medical waste by a transporter, transfer, storage, treatment, or disposal facility operator.
42. "Transportation management plan" means the transporter's written plan consisting of both of the following:
    a. The procedures used by the transporter to minimize the exposure to employees and the general public to regulated medical waste throughout the process of collecting, transporting and handling.
    b. The emergency procedures used by the transporter for handling spills or accidents.
43. "Transporter" means a person engaged in the hauling of regulated medical waste from the point of generation to an intermediate approved storage facility or to an approved treatment or disposal facility.
44. "Treat" or "treatment" means incinerating, autoclaving or using the alternative treatment technologies prescribed in this Article.
45. "Treated medical waste" means regulated medical waste that has been treated and that meets the treatment standards of R18-13-1415. Treated medical waste that requires no further processing is considered solid waste and may be disposed of in a municipal solid waste landfill.
46. "Treater" means a person, also known as an operator, who receives solid waste facility plan approval for the purpose of operating a medical waste treatment facility to treat regulated medical waste that was generated off-site.
47. "Treatment certification statement" means the written document provided by either a generator who treats regulated medical waste on-site or by a treater, to inform a solid waste disposal or recycling facility that regulated medical waste has been treated as prescribed in this Article, and therefore no longer subject to regulation under this Article.
48. "Treatment standards" means the level of microbial inactivation to be achieved for a specific type of regulated medical waste as required by this Article.
49. "Universal biohazard symbol" means a representation that conforms to the design shown in 29 CFR 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1997) incorporated by reference and on file with the Secretary of State. This incorporation by reference contains no future editions or amendments. A copy of this referenced material may be obtained at: the Department of Environmental Quality.
50. "Vehicle not dedicated to the transportation of regulated medical waste but which is engaged in commerce" means a motor vehicle or a trailer that is pulled by a motor vehicle, that is, used on a temporary basis for the transportation of regulated medical waste, and that has the primary purpose of transporting of goods that are not solid waste or regulated medical waste.

18-13-1402. Applicability

A. This Article applies to the following:
1. A generator who treats regulated medical waste on-site, before disposing of it as treated medical waste, and to any equipment used for that purpose. A generator who treats on-site shall meet the requirements in R18-13-1405.
2. A generator who contracts with a medical waste treatment facility for the purpose of treating regulated medical waste. This generator shall meet the requirements of R18-13-1406.
3. A person who transports regulated medical waste and any motor vehicle used for that purpose.
4. A medical waste treatment facility operator, a medical waste treatment facility, and any equipment used for that purpose.
5. A person who provides alternative medical waste treatment technology for the purpose of treatment, and to any technology used for that purpose.

6. A person in possession of regulated medical waste if the waste does not meet the treatment standards in R18-13-1415.
7. An operator of a municipal solid waste landfill who accepts untreated regulated medical waste.

B. Regulated medical waste set out for collection does not apply to the manner in which the generator collects, handles and stores medical waste inside the generator's place of business.

C. Treated medical waste is considered solid waste as described in A.R.S. Title 49, Chapter 4.

R18-13-1403. Exemptions; Partial Exemptions

A. The following are exempt from the requirements of this Article:
1. Law enforcement personnel handling regulated medical waste for law enforcement purposes.
2. A person in possession of radioactive material.
3. A person who returns unused medical sharps to the manufacturer.

B. The following are conditionally exempt from the requirements of this Article:
1. Human corpses, remains, and anatomical parts that are intended for interment or cremation. However, if medical sharps are generated during the preparation of the human remains, they must be disposed of as prescribed by this Article.
2. A person who operates an emergency rescue vehicle, an ambulance, or a blood service collection vehicle if the regulated medical waste is transported to a central collection facility. The central collection facility is considered to be the point of generation for packaging, treatment and disposal.
3. A person who sends used medical sharps to a treatment facility if properly packaged and transported via the United States Postal Service or private shipping agent.
4. A person who discharges discarded drugs and liquid and semi-liquid regulated medical wastes, excluding cultures and stocks, to the sanitary sewer system if the operator of the waste water sewer system and treatment facility allows, permits, authorizes or otherwise approves of the discharges.
5. A person who possesses hazardous waste regulated by A.R.S. Title 49, Chapter 5.
6. A person who resides in a private, public, or semi-public residence and who generates regulated medical waste in the administration of self-care. This exemption does not apply to a person residing in a facility licensed by the Arizona Department of Health Services.
7. A public health care worker who uses a multi-purpose vehicle in the conduct of routine business other than transporting waste, is exempt from the requirements of R18-13-1409 if the health care worker complies with all of the following:
   a. Packages the regulated medical waste according to R18-13-1407.
   b. Secures the packaged regulated medical waste within the vehicle so as to minimize spills.
   c. Transports the regulated medical waste to the agency's central collection site or to a medical waste treatment or disposal facility.
   d. Decontaminates the vehicle when it shows visible signs of contamination.
   e. Secures the vehicle to prevent unauthorized contact with the regulated medical waste.
8. A person who transports regulated medical waste between multiple properties owned or operated by the same owner or governmental entity is exempt from the requirements of 18-13-1407 if the person complies with subsection (7) (a)-(e).

C. The following are exempt from some of the requirements of this Article:
1. A generator who treats regulated medical waste on-site and who accepts for treatment medical waste described in paragraph (B)(6) of this section is exempt from the requirement to obtain solid waste facility plan approval described in R18-13-1410.
2. A generator who contracts with a permitted transporter to transport regulated medical waste to a medical waste treatment or disposal facility is relieved of any obligation to retrieve and treat improperly disposed regulated medical waste after the transporter accepts possession.
3. A generator who self-hauls regulated medical waste to an approved medical waste treatment or disposal facility is relieved of any obligation to retrieve and treat regulated medical waste that is improperly disposed, after the treater or landfill operator accepts possession.
4. A person who is in possession of regulated medical waste that also contains radioactive material is exempt from the packaging and storage requirements of this Article if the packaging and storage requirements of R12-1-101 through R12-1-112 are more restrictive. A person shall not treat and dispose of regulated medical waste until after the radioactive component has decayed in storage as provided in R12-1-101 through R12-1-112.

R18-13-1404. Transition and Compliance Dates

A. Unless otherwise specified in subsections (B) through (H), the date for compliance with this Article by generators, transporters, treaters, providers of alternative medical waste technology, and persons in possession of untreated regulated medical waste is the effective date of this Article.

B. A person who provides alternative medical waste treatment technology in operation by a generator before the effective date of this Article shall perform all of the following:
1. Register the alternative medical waste technology with the Department as described in R18-13-1414 within 90 days after the effective date of this Article.
2. After 90 days of the effective date of this Article, not provide alternative medical waste treatment technology to additional generators until Departmental registration is received.
3. After Departmental registration is received, provide to all generators using the alternative treatment technology a copy of the registration certification and the alternative technology manufacturers specifications as required in R18-13-1414.

C. A generator who utilizes alternative medical waste treatment technology before the effective date of this Article shall obtain, within 180 days after the effective date of this Article, the Departmental registration number, and equipment specifications as described in R18-13-1414 from the technology provider. If documentation of Departmental registration is not on file with the generator, regulated medical waste treated 180 days after the effective date of this Article using the unregistered alternative treatment technology is considered to be untreated regulated medical waste.

D. A generator who utilizes incineration or steam sterilization for on-site treatment of regulated medical waste before the effective date of this Article, may continue to do so after the effective date if the treatment requirements of R18-13-1415

and the on-site treatment requirements of R18-13-1405 are met.

E. A transporter of regulated medical waste before the effective date of this Article shall register, within 90 days after the effective date of this Article, as required in R18-13-1409(A).

F. An operator of a medical waste storage facility, who has obtained approval as a solid waste facility as described by A.R.S. § 49-762 and who has obtained that approval before the effective date of this Article, may continue to store regulated medical waste if the facility complies with the design and operation standards described in R18-13-1411. The addition of a refrigeration unit is a Type II change as described in R18-13-1413(A)(2).

G. An operator of a medical waste transfer facility must obtain solid waste facility plan approval that meets the requirements of R18-13-1410 within 180 days after the effective date of this Article.

H. An operator of a medical waste treatment facility who has obtained Departmental plan approval to operate a medical waste treatment facility and who has obtained that approval before the effective date of this Article may continue to operate under that plan approval if both of the following are met:

1. The treater complies with the treatment standards of R18-13-1415 and the record keeping requirements of R18-13-1412, except as noted in the paragraph below.
2. If the treater determines that the waste is not being treated to the applicable treatment standards of R18-13-1415, the treater shall inform the Department within 2 working days of this determination, and within 30 working days enter into an administrative consent order to bring the facility into compliance.

I. An operator of an existing municipal solid waste landfill who intends to accept untreated regulated medical waste shall submit a notice of a Type 3 change and an amended facility plan within 180 days after the effective date of this Article.

J. Notwithstanding subsection (H), if the Department determines that an updated solid waste facility plan is required, a treater shall submit an updated plan within 180 days after receiving the Department's determination. The treater may continue to operate under the conditions specified in subsection (F) of this Section while the Department reviews and determines whether to approve or deny the updated plan.

K. After the effective date of this Article, solid waste facility plan approval under A.R.S. § 49-762.03 is required for a new medical waste treatment or disposal facility before construction.

R18-13-1405. Regulated Medical Waste Treated On-Site

A. A person who treats regulated medical waste on-site shall use incineration, steam sterilization, or an alternative medical waste treatment method prescribed in R18-13-1415(A).

B. A generator who uses:

1. Incineration shall follow the requirements of subsections (C) and (F),
2. Autoclaving shall follow the requirements of subsections (D) and (F), or
3. An alternative treatment method shall follow the requirements of subsections (E) and (F).

C. A generator who incinerates regulated medical waste on-site shall comply with all of the following conditions:

1. Obtain a permit if required by the local or state air quality agency having jurisdiction.
2. Reduce the regulated medical waste, excluding metallic items, into carbonized or mineralized ash.
3. Perform a waste determination of incinerator ash as required by hazardous waste rules adopted under A.R.S. Title 49, Chapter 5.
4. Dispose of the non-hazardous waste incinerator ash at a Department approved municipal solid waste landfill.

D. A generator who autoclaves regulated medical waste on-site shall comply with all of the following conditions:

1. Further process any recognizable human tissue, organs, body parts, and animals to render such waste non-recognizable.
2. Operate the autoclave at the manufacturer's specifications appropriate for the quantity and density of the load, and sufficient to achieve sterilization, as defined in R18-13-1401.
3. Keep records of operational performance levels for 6 months after each cycle. Operational performance level record keeping shall include all of the following:
   a. Duration of time for each treatment cycle.
   b. The temperature and pressure maintained in the treatment unit during each cycle.
   c. The method used to determine parameters as set forth in the manufacturer's specifications.
   d. The method used to confirm microbial inactivation and the test results.
   e. Any other operating parameters as set forth in the manufacturer's specifications.
4. Keep records of equipment maintenance for the duration of equipment use that include the date and result of all equipment calibration and maintenance.

E. A generator who uses an alternative treatment method on-site shall comply with all of the following conditions:

1. Use only alternative treatment methods registered under R18-13-1414.
2. Further process any recognizable human tissue, organs, body parts, and animals to render this waste non-recognizable.
3. Follow the manufacturer's specifications for equipment operation.
4. Display or supply upon request all of the following:
   a. The Departmental registration number for the alternative medical waste treatment technology and the type of regulated medical waste that the equipment is registered to treat.
   b. The equipment specifications that include all of the following:
      i. The operating procedures for the equipment that ensure the equipment complies with the treatment standards described in this Article for the type of waste treated.
      ii. The instructions for equipment maintenance, testing and calibration that ensure the equipment complies with the treatment standards described in this Article for the type of waste treated.
5. Maintain a training manual regarding the proper operation of the equipment.
6. Maintain a treatment record consisting of a log of the volume of medical waste treated and a schedule of calibration and maintenance performed under the manufacturer's specifications.
7. Maintain treatment records for 6 months after the treatment date for each load treated.
8. Maintain the equipment specifications for the duration of equipment use.

F. A generator shall do all of the following:

1. Package the treated medical waste.
   a. According to the waste collection agency's requirements;
   b. Attach to the package or container a label, placard, or tag with the following words: "This medical waste has been treated as required by the Arizona Department of Environmental Quality standards" before placing the treated medical waste out for collection. The generator shall ensure that the label, placard, or tag is easily readable at a distance of 10 feet.
2. Upon request of the solid waste collection agency or municipal solid waste landfill, provide a certification that the treated medical waste meets the standards of R18-13-1415.
3. Make treatment records available for Departmental inspection upon request.
4. Dispose of the treated medical waste at a Department approved municipal solid waste landfill or, if the waste was prepared for recycling as required by R18-13-1416, dispose at a Department approved solid waste recycling facility.

G. Medical sharps shall be rendered incapable of being reused before packaging.

H. Encapsulation of regulated medical waste or medical sharps waste and subsequent disposal as solid waste is acceptable if the agent used to solidify and encase the contents meets the treatment standards of R18-13-1415.

R18-13-1406. Regulated Medical Waste Transported Off-Site for Treatment

A. A generator of regulated medical waste shall package the waste as described in R18-13-1407 before self-hauling or before setting the waste out for collection by a transporter.

B. A generator shall obtain a tracking document from the transporter for each waste load accepted by the transporter. In addition, a generator shall keep a copy of the tracking document for 1 year from the date of acceptance by the transporter. The tracking document shall contain all of the following information:
   1. Name and address of the transporter.
   2. Quantity of regulated medical waste collected by weight, volume, or number of containers.
   3. Identification number attached to bags or containers.
   4. Date the regulated medical waste is collected.

R18-13-1407. Packaging of Regulated Medical Waste

A. A generator who sets regulated medical waste out for collection for off-site treatment or disposal shall package the regulated medical waste in either of the following:
   1. A red disposable plastic bag that is:
      a. Of sufficient thickness to prevent breakage.
      b. Sealed to prevent leakage of contents during storage, handling, or transport.
      c. Placed in a secondary container. This container shall be constructed of materials that will prevent breakage of the bag in storage and handling during collection and transportation and which bears the universal biohazard symbol. The secondary container may be either disposable or reusable. "Universal biohazard symbol" means a representation that conforms to the design shown in 29 C F R 1910.145(f)(8)(ii) (Office of the Federal Register, National Archives and Records Administration, July 1, 1997) incorporated by reference and on file with the Secretary of State. This incorporation by reference contains no future editions or amendments. A copy of this referenced material may be obtained at: the Department of Environmental Quality.
   2. A reusable container or bag that bears the universal biohazard symbol and that is:
      a. Leak-proof on all sides and bottom, closed with a fitted lid, and constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents and hot water.
      b. Composed of disposable packaging and liners shall be managed as regulated medical waste and not reused.
      c. Used for the storage or transport of regulated medical waste and designated for reuse once emptied, shall be decontaminated unless the inner surfaces of the container have been protected from contamination by disposable liners, bags, or other devices removed with the waste. "Decontamination" means agitation to remove visible soil combined with 1 of the following:
         i. Exposure to hot water at a temperature of at least 180 degrees Fahrenheit for a minimum of 15 seconds.
         ii. Exposure to an EPA approved chemical disinfectant used under established protocols and regulations.
         iii. Any other manner that the Department determines is acceptable, if the determination of acceptability is made in advance of the decontamination.

B. Any container used for the storage or transport of regulated medical waste that is not capable of being decontaminated as described in subsection (A)(2)(c), shall be handled as regulated medical waste.

C. A generator shall not use reusable containers for any purpose other than the storage of regulated medical waste.

R18-13-1408. Storage of Regulated Medical Waste

A. A generator may place a container of regulated medical waste alongside a container of solid waste if the regulated medical waste is identified and not allowed to co-mingle with the solid waste. The storage area shall not be used to store substances for human consumption or for medical supplies.

B. A generator shall provide a storage area for the storage of regulated medical waste until the waste is collected and shall meet both of the following:
   1. Secure the storage area by a door and lock if the storage area is located indoors or a fenced in area with a gate and lock if the storage area is located outdoors.
   2. Display the universal biohazard symbol and post warning signs worded as follows for medical waste storage areas: (in English) "CAUTION -- BIOHAZARDOUS MEDICAL WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and (in Spanish) "PRECAUCION -- ZONA DE ALMACENAMIENTO DE DESPERDICIOS BIOLOGICOS PELIGROSOS -- PROHIBIDA LA ENTRADA A PERSONAS NO AUTORIZADAS."

C. Beginning at the time the waste is set out for collection, a generator who stores regulated medical waste shall comply with all of the following:
   1. Keep putrescible regulated medical waste unrefrigerated if it does not create a nuisance. Putrescible regulated

medical waste may be kept longer than 7 days if it is refrigerated at 40° F. or less.

2. Store regulated medical waste for longer than 90 days only if the generator has obtained facility plan approval under A.R.S. § 49-762 and is in compliance with the design and operational requirements described in R18-13-1412.
3. Keep the storage area free of contamination.
4. Protect regulated medical waste from contact with water, precipitation, wind, or animals. The waste shall not provide a breeding place or a food source for insects or rodents.
5. Handle spills by re-packaging the regulated medical waste, re-labeling the containers and decontaminating any soiled surface as described in R18-13-1407(A)(2)(c).
6. Notwithstanding paragraph 1 of this subsection, if odors become a problem, minimize objectionable odors and off-site migration of odors. If a generator complies with (C)(1) through (C)(5) of this subsection and the facility is unable to control the odor, the Department may require waste removal after 3 days or waste refrigeration.

R18-13-1409. Transportation of Regulated Medical Waste

A. A transporter shall register with the Department registration in addition to possessing a permit, license, or approval if required by a local health department, environmental agency, or other governmental agency with jurisdiction.

B. Upon receiving all of the following information from a transporter, the Department shall issue registration after assigning a registration number to the transporter:
1. The name, address and telephone number of the transportation company or entity.
2. All owners' names, addresses, and telephone numbers.
3. All names, addresses, and telephone numbers of any agents authorized to act on behalf of the owner.
4. A copy of either the certificate of disclosure required by A.R.S. § 49-109 or an acknowledgment that this disclosure is not required.
5. Photocopies or other evidence of the issuance of a permit, license, or approval where required by a local health department, environmental agency, or other governmental agency with jurisdiction as described in subsection (A).
6. A copy of the transportation management plan required in subsection (C).

C. A person who transports regulated medical waste shall maintain in each transporting vehicle at all times a transportation management plan consisting of both of the following:
1. Routine procedures used to minimize the exposure to employees and the general public to regulated medical waste throughout the process of collecting, transporting, and handling.
2. Emergency procedures used for handling spills or accidents.

D. A transporter who accepts regulated medical waste from a generator shall leave a copy of the tracking document described in R18-13-1406(B) with the person from whom the waste is accepted. A copy of the tracking document accompanies the person who has physical possession of the regulated medical waste. Upon delivery to a Department approved transfer station, storage facility, treatment or disposal facility, the transporter shall obtain a signed copy of the tracking document signifying acceptance of the regulated medical waste.

E. A transporter who transports regulated medical waste in a vehicle dedicated to the transportation of regulated medical waste shall ensure that the cargo compartment can be secured to limit access to authorized persons. In addition, the cargo compartment shall be constructed in compliance with 1 of the following:
1. Have a fully enclosed, leak-proof cargo compartment consisting of a floor, sides, and a roof that are made of an impervious material, or material that is otherwise sealed and physically separated from the driver's compartment.
2. Haul a fully enclosed, leak-proof cargo box made of an impervious and non-porous material.
3. Tow a fully enclosed leak-proof trailer made of an impervious and non-porous material.

F. A person who transports regulated medical waste in a vehicle not dedicated to the transportation of regulated medical waste, but that is used longer than 30 days in commerce, shall comply with the following:
1. Subsection (A) and (E).
2. Decontaminate the vehicle before it is used again.

G. A person who transports regulated medical waste shall comply with all of the following:
1. Accept only regulated medical waste packaged as described in R18-13-1407.
2. Accept only regulated medical waste accompanied by a tracking form as described in R18-13-1406(B).
3. Deliver regulated medical waste to a Department approved regulated medical waste storage, transfer, treatment or disposal facility within 24 hours of collection or refrigerate the waste at 40° F. or less until delivery.
4. Not hold regulated medical waste longer than 96 hours in a refrigerated vehicle unless the vehicle is parked at a Department approved facility.
5. Not unload, reload, or transfer the regulated medical waste to another vehicle in any location other than a Department approved facility, except in emergency situations. Combination vehicles or trailers may be coupled and uncoupled to another cargo vehicle or truck trailer as long as the regulated medical waste is not removed from the cargo compartment.
6. Securely close all discharge openings during operation of the vehicle.
7. Lock the cargo compartment at all times when regulated medical waste is present except during loading or unloading.

R18-13-1410. Medical Waste Storage, Transfer, Treatment, and Disposal Facilities; Facility Plan Approval Requirement

A. A person shall obtain solid waste facility plan approval from the Department as described in A.R.S. § 49-762 to construct any facility that will be used to store, transfer, treat, or dispose of regulated medical waste that was generated off-site. Plan approval shall be obtained before starting construction of the medical waste treatment or disposal facility. This requirement also applies to solid waste facilities for which an operator self-certifies under A.R.S. § 49-762.05, if the facility also will receive regulated medical waste.

B. If an air quality permit is required for the facility under A.R.S. Title 49, Chapter 3, then evidence of that air quality permit, or evidence of that air quality permit application shall be included in the application for solid waste facility plan approval.

R18-13-1411. Medical Waste Storage and Transfer Facilities;

Design and Operational Requirements.
An operator of a storage facility or transfer facility shall be in compliance with all of the following design and operation requirements:

1. The facility shall be designed so that regulated medical waste is always handled and stored separately from other types of solid waste if accepted at the facility.
2. Display prominently the universal biohazard symbol and post warning signs worded as described in R18-13-1401.
3. Construct the storage area from smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfecting agents and hot water.
4. Protect regulated medical waste from contact with water, precipitation, wind, or animals.
5. Specify in the application for facility plan approval the maximum storage time that regulated medical waste shall remain at the facility. If the regulated medical waste will be stored for longer than 24 hours, the facility shall be equipped with a refrigerator to refrigerate the regulated medical waste. The operator of the facility shall maintain the refrigerator at 40° F. or lower.
6. Accept regulated medical waste only if it is accompanied by the tracking form. The operator shall sign the tracking form and keep a copy of the acceptance documentation for a period of 1 year;
7. Accept regulated medical waste if it is packaged as described in R18-13-1407. If a regulated medical waste container is damaged or leaking, improperly labeled or otherwise unacceptable, a transfer facility operator shall do 1 of the following:
   a. Reject the waste and return it to the generator.
   b. Accept the waste and immediately repackage it as described in R18-13-1407(A).
8. Decontaminate the storage area as described in R18-13-1407(A)(2)(c) on a regular basis and after any spills.

R18-13-1412. Medical Waste Treatment Facilities; Design and Operational Requirements

A. An operator who applies for facility plan approval shall demonstrate compliance with all of the following:
   1. Documentation for all of the following equipment specifications:
      a. Equipment specifications that identify the proper type of medical waste to be treated in the equipment and any design or equipment restrictions.
      b. Manufacturer's specifications and operating procedures for the equipment that describe the type and volume of waste to be treated, monitoring data of the treatment process, and calibration and testing of the equipment, that detail the capability of the equipment to achieve the treatment standards described in R18-13-1415.
      c. Instructions for equipment maintenance, testing, and calibration that ensure the equipment achieves the treatment standards described in R18-13-1415.
      d. Training manual for the equipment.
      e. Written certification from the manufacturer stating that the equipment when operated properly is capable of achieving the treatment standards described in R18-13-1415.
   2. Submit to the Department and have readily available at the facility, an operations procedure manual describing how the waste will be handled from the time it is accepted by the treater through the treatment process and final disposition of the treated waste. The operation procedures manual shall include all of the following:
      a. Provisions for treating regulated medical waste within 24 hours of receipt or refrigerating immediately at 40° F. or lower upon determination that treatment or disposal will not occur within 24 hours.
      b. A contingency plan if the treatment equipment is out of service for an extended period of time. The plan shall address the manner and length of storage of the waste. The length of time the regulated medical waste can remain in storage shall not exceed 90 days and shall be based on the capacity of the equipment to treat the backlog of stored waste together with the ongoing operations. If the 90 day time-frame will be exceeded, the operator shall either stop accepting waste until the backlog is treated, or contract with another treatment facility to assist in treating the waste.
      c. Procedures for handling hazardous chemicals, radioactive waste, and chemotherapy waste. The plan shall provide for scanning regulated medical waste with a Geiger counter and handling waste above background level in compliance with state and federal law.
      d. Procedures for cleaning and decontaminating the processing area of waste at the end of every working day unless the facility is approved to process waste on a 24 hour basis. If the facility is approved to process waste on a 24 hour basis, the processing area shall be cleared of waste and decontaminated after every 24 hours of operation.
   3. Accept regulated medical waste from a transporter only if the waste is accompanied by a tracking form, and comply with both of the following:
      a. Sign the tracking document and keep a copy of the acceptance documentation for a period of 1 year.
      b. If a regulated medical waste container is damaged or leaking, improperly labeled, or otherwise unacceptable, a treater shall do 1 of the following:
         i. Reject the waste and return it to the generator.
         ii. Accept the waste and transfer it directly from the transporting vehicle to the treatment processing unit.
         iii. If the waste will not be treated immediately, re-package the waste for storage.
   4. Assure that the facility is designed to meet both of the following:
      a. Any floor or wall surface in the processing area of the facility which may come into contact with regulated medical waste is constructed of a smooth, easily cleanable material that is impervious to liquids.
      b. The floor surface in the treatment and storage area shall either have a curb of sufficient height to contain spills or shall slope to a drain that connects to an approved sanitary sewage system, approved septic tank system, or collection device.
   5. Store regulated medical waste as required in R18-13-1408(E).
   6. Comply with all of the following if the treatment method is incineration:
      a. Reduce the incinerated medical waste, excluding metallic items, into carbonized or mineralized ash by incineration.

b. Perform a waste determination of the ash to determination whether the ash is hazardous as described in R18-8-262.

7. Keep records of equipment maintenance and operational performance levels for 3 years. The records shall include the date and result of all equipment calibration and maintenance. Operational performance level records shall include duration of time for each treatment cycle as follows:
   a. For steam treatment and microwaving treatment records, both the temperature and pressure maintained in the treatment unit during each cycle, and the method used for confirmation of temperature and pressure.
   b. For chemical treatment, a description of the solution used.
   c. For incineration, the temperature maintained in the treatment unit during operation.
   d. Any other operating parameters as set forth in the manufacturer's specifications.
   e. A description of the method used and a copy of the test results.

B. The treater shall make treatment records available for Departmental inspection upon request.

R18-13-1413. Changes to Approved Medical Waste Facility Plans

A. As required by A.R.S. § 49-762.06, before making any change to an approved facility plan a treatment facility operator shall submit a notice to the Department stating which of the following categories of change is requested:
   1. A Type 1 change to an approved medical waste facility plan is a change not described in subsections (2), (3), or (4).
   2. A Type 2 change to an approved medical waste facility plan is a change in which treatment equipment is replaced with equal or like equipment, that results in either no increase to treatment capacity or the addition of equipment that is not directly used in treatment process.
   3. A Type 3 change to an approved medical waste facility plan is a change described by 1 of the following:
      a. Treatment equipment is added, resulting in less than a 25% increase in treatment capacity.
      b. The storage area is enlarged resulting in less than a 25% increase in storage capacity.
      c. A change in treatment technology.
   4. A Type 4 change to an approved medical waste facility plan is a change described by 1 of the following:
      a. Treatment equipment is added, resulting in a 25% or more increase in treatment capacity.
      b. The storage area is enlarged resulting in a 25% or more increase in storage capacity.
      c. Treatment equipment is added, that requires an environmental permit.
      d. An expansion of the treatment facility onto land not previously described in the approved plan.

B. As required by A.R.S. § 49-762.06, a treatment facility operator who has identified the change as described in subsection (A) shall comply with 1 of the following:
   1. For a Type 1 change, make the change without notice to, or approval by the Department.
   2. For a Type 2 change, before making any change, provide written notification that describes the change to the Department. The addition of refrigeration units only for compliance with this Article is a Type 2 change for which no Departmental approval is required.
   3. For a Type 3 or Type 4 change, submit an amended plan to the Department for approval before making any change. Departmental approval is required prior to making any change.

R18-13-1414. Alternative Medical Waste Treatment Methods: Registration and Equipment Specifications

A. A manufacturer or its agent who applies for alternative medical waste treatment method registration shall submit to the Department all of the following:
   1. The manufacturer or company name and address.
   2. The name, address, and telephone number of the person who submits the application.
   3. A description of the alternative medical waste treatment method.
   4. A list of any other states in which the treatment method is used, including a copy of any state approvals.
   5. A description of by-products generated as result of the alternative treatment method.
   6. A certification statement that the contents of the application are true and accurate to the knowledge and belief of the applicant.
   7. Written documentation that demonstrates that the alternative medical waste treatment method is capable of compliance with the treatment standards in this Article for the type of waste treated. The demonstration shall be made by a laboratory independent of any oversight activities by the manufacturer.
   8. The manufacturer's equipment specifications for the alternative medical waste treatment method being registered, including all of the following:
      a. Unit model number, or serial number.
      b. Equipment specifications that identify the proper type of regulated medical waste to be treated by the equipment and any design or equipment restrictions.
      c. Operating procedures for the equipment that ensure the equipment complies with the treatment standards described in this Article for the type of waste treated.
      d. Instructions for equipment maintenance, testing and calibration that ensure the equipment complies with the treatment standards described in this Article for the type of waste treated.

B. The Department shall make a determination whether or not to approve the registration application. If the Department approves the application, it shall issue an alternative medical waste treatment method registration number to the applicant. Only an alternative technology method with a valid Department issued registration number shall qualify as meeting the requirements of this Article.

R18-13-1415. Treatment Standards, Quantification Of Microbial Inactivation And Efficacy Testing Protocols

A. Regulated medical waste treated by 1 of the following methods is treated medical waste:
   1. Incineration, that reduces the incinerated medical waste, excluding metallic items, into carbonized or mineralized ash.
   2. Steam sterilization or other sterilization, that achieves complete elimination or destruction of all forms of microbial life.
   3. An alternative medical waste treatment method that meets the treatment standards set forth in subsection (E).

B. A person who generates the following regulated medical waste categories shall meet all the following additional requirements:

1. Ensure that cultures and stocks are incinerated, steam sterilized or treated by an alternative medical waste treatment method that achieves sterilization.
2. Ensure that chemotherapy waste is incinerated or disposed of in either an approved solid waste or hazardous waste disposal facility.
3. If grinding is used in combination with another treatment method described in this Article, ensure that it is conducted in a closed system to prevent exposure to humans and the environment. If grinding is used for medical sharps, this grinding shall render the medical sharps incapable of being reused.
4. Handle medical sharps according to both of the following:
   a. Render incapable of being reused.
   b. Ensure treatment by 1 of the following:
      i. Sending to a Departmental approved medical waste treatment facility.
      ii. Packaging as instructed by the transporter and send them to a treatment facility via a mail-back system. An Arizona treatment facility shall render medical sharps incapable of being reused.
      iii. Using an encapsulation agent that meets the standards of subsection (B) before disposal in a landfill.

C. A person shall not use compaction as a treatment method for regulated medical waste.

D. A treater shall ensure that treatment achieves either of the following treatment standards:

1. Inactivation is required to be demonstrated for vegetative bacteria, fungi, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log 10 reduction or greater.
2. Inactivation is required to be demonstrated of *B. stearothermophilus* spores or *B. subtilis* spores at a 4 Log 10 reduction or greater.

E. A treater utilizing an alternative treatment method shall use 1 or more of the following representative biological indicators to demonstrate treatment efficacy:

1. One or more of the following representative microorganisms from each microbial group shall be used to determine if microbial inactivation requirements are met:
   a. Vegetative bacteria:
      i. Staphylococcus aureus (ATCC 6538),
      ii. Pseudomonas aeruginosa (ATCC 15442).
   b. Fungi:
      i. Candida albicans (ATCC 18804),
      ii. Penicillium chrysogenum (ATCC 24791), or
      iii. Aspergillus niger.
   c. Viruses: MS-2 Bacteriophage (ATCC 15597-B1).
   d. Parasites: Cryptosporidium spp. oocysts.
   e. Mycobacteria:
      i. Mycobacterium terrae,
      ii. Mycobacterium phlei, or
      iii. Mycobacterium bovis (BOG) (ATCC 35743).
2. Spores from 1 of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems:
   a. B. stearothermophilus (ATCC 7953),
   b. B. subtilis (ATCC 19659).

D. A treater utilizing an alternative treatment method shall quantify microbial inactivation as follows:

1. Microbial inactivation, or "kill" efficacy is equated to "Log^{10} Kill" that is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment. This definition is equated as:

   $Log^{10}Kill = Log^{10}(cfu/g\ "I") - Log^{10}(cfu/g\ "R")$

   where:

   $Log^{10}Kill$ is equivalent to the term Log^{10} reduction,

   "I" is the number of viable test microorganisms introduced into the treatment unit,

   "R" is the number of viable test microorganisms recovered from the treatment unit, and

   "cfu/g" are colony forming units per gram of waste solids.
2. For those treatment processes that can maintain the integrity of the biological indicator carrier of the desired microbiological test strain, biological indicators of the required strain and concentration may be used to demonstrate microbial inactivation. Quantification is evaluated by growth or no growth of the cultured biological indicator.
3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator, quantitative measurement of microbial inactivation requires a two step approach: Step 1 "Control" and Step 2 "Test". The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.
   a. Step 1:
      i. Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.
      ii. Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the treatment agent (that is, heat, chemicals).
      iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.
      iv. Plate the recovered microorganism suspensions to quantify microbial recovery. The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the treatment agent.
      v. The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction, either a 6 Log^{10} reduction for vegetative microorganisms or a 4 Log^{10} reduction for bacterial spores. This can be defined by the following equation:

      $Log^{10}RC = Log^{10}IC - Log^{10}NR$

      or

      $Log^{10}NR = Log^{10}IC - Log^{10}RC$

      where:

$Log^{10}RC$ is greater than 6 for vegetative microorganisms and greater than 4 for bacterial spores and where:

$Log^{10}RC$ is the number of viable "Control" microorganisms in colony forming units per gram of waste solids recovered in the non-treated processed waste residue;

$Log^{10}IC$ is the number of viable "Control" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit;

$Log^{10}NR$ is the number of "Control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated processed waste residue. $Log^{10}NR$ represents an accountability factor for microbial loss.

b. Step 2:

i. Use microbial cultures of the same concentration as in Step 1.

ii. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the treatment agent.

iii. Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

iv. Plate recovered microorganism suspensions to quantify microbial recovery.

v. From data collected from Step 1 and Step 2, the level of microbial inactivation, "Log10 Kill", is calculated by employing the following equation:

$Log^{10}Kill = Log^{10}IT - Log^{10}NR - Log^{10}RT$

where:

$Log^{10}Kill$ is equivalent to the term Log^{10} reduction;

$Log^{10}IT$ is the number of viable "Test" microorganisms in colony forming units per gram of waste solids introduced into the treatment unit. $Log^{10}IT = Log^{10}IC$;

$Log^{10}NR$ is the number of "Control" microorganisms in colony forming units per gram of waste solids which were not recovered in the non-treated processed waste residue;

$Log^{10}RT$ is the number of viable "Test" microorganisms in colony forming units per gram of waste solids recovered in treated processed waste residue.

F. Any methodology employed to determine treatment efficacy of the technology shall assure required microbial inactivation and shall assure that the protocols are congruent with the treatment method. Acceptable demonstration of compliance is required to be provided by an independent testing laboratory.

R18-13-1416. Recycled Materials.

A. Once a generator places regulated medical waste in a red bag as required in R18-13-1409, no one shall remove any of the regulated medical waste from the bag until the regulated medical waste has been treated as required in R18-13-1415.

B. A generator of regulated medical waste intending to recycle any portion of the regulated medical waste shall keep that portion of regulated medical waste separate from that portion of regulated medical waste that will not be recycled. The generator shall do either of the following:

1. Treat the regulated medical waste intended for recycling as required in R18-13-1415 before sending the treated medical waste to a recycler.
2. Follow the requirements R18-13-1406, R18-13-1407, and R18-13-1408, before either contracting with a transporter to haul or self-hauling the regulated medical waste to a treatment facility for treatment. After treatment, the treated medical waste may be sent to a recycler.

R18-13-1417. Disposal Facility Operational Requirements

An operator of a municipal solid waste landfill that accepts untreated regulated medical waste shall demonstrate compliance with all of the following in its facility plan:

1. Only accept regulated medical waste if packaged according to R18-13-1407.
2. Keep the regulated medical waste disposal area separate from the general purpose disposal area.
3. Clearly label the regulated medical waste disposal area informing persons that the disposal area contains untreated medical waste.
4. Do not drive directly over deposited medical waste, achieve compaction by first spreading a layer of soil that is sufficiently thick to prevent compaction equipment from coming into direct contact with the waste, and to prevent compaction equipment from dragging waste over the area.
5. Cover the regulated medical waste with 6 inches of compacted soil at the end of working day or more often as necessary to prevent vector breeding and odors.
6. Do not allow salvaging of untreated regulated medical waste from the landfill.